CLINICAL
NUTRITION

DOI: 10.12957/demetra.2019.38198

DEMETRA
Alimentação, Nutrição & Saúde

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# Are the nutritional status and tube feeding associated with quality of life in oncologic patients on palliative care?

## *O estado nutricional e a alimentação via sonda estão associados à qualidade de vida em pacientes oncológicos em cuidados paliativos?*

**Abstract**

***Objective:*** To evaluate the association of nutritional status and tube feeding on the quality of life of oncology patients in palliative care. ***Methods:*** Oncological patients enrolled in the Palliative Care Program of a university hospital (n=70) participated in the study. Nutrition therapy data (tube feeding or oral feeding) were collected through a previously structured questionnaire. The nutritional evaluation was performed by the Patient-Generated Subjective Global Assessment (PG-SGA). In addition, the EORTC QLQ-C15-PAL questionnaire was used to assess the quality of life. ***Results:*** Of the 70 patients, 58.6% (n=41) were males, aged between

31-101 years. The most frequent tumors were in head and neck (18.6%; n=13). The frequency of malnutrition was 87.2% (n=61). Regarding the feeding route, 84.3% (n=59) received oral feeding and 15.7% (n=11), tube feeding. The mean score for the Global Quality of Life domain was 66.6, regardless of the dietary route. Malnourished patients had a higher score for the Physical Function domains (34.9±30; p=0.005) and Dyspnea (20.7±29.9; p=0.02). Tube feeding was associated with a higher frequency of nausea (Median = 33.3; p=0.014). ***Conclusions:*** A high frequency of malnutrition (87.2%) and a low frequency of tube feeding (15.7%) was observed. Nutritional status and tube feeding were not associated with the Global Quality of Life of cancer patients in palliative care. However, malnutrition was associated with lower scores of physical function and dyspnea, while tube feeding was associated with a higher incidence of nausea.

**Keywords:** Palliative care; Oncology; Nutritional therapy; Tube feeding; Enteral nutrition; Quality of life.

**Resumo**

***Objetivo:*** Avaliar a associação do estado nutricional e da alimentação via sonda na qualidade de vida de pacientes oncológicos em cuidados paliativos. ***Métodos:*** Participaram do estudo pacientes oncológicos cadastrados no Programa de Cuidados Paliativos de um hospital universitário (n=70). Informações sobre a terapia nutricional (alimentação por sonda ou alimentação via oral) foram coletadas por meio de um questionário previamente estruturado. A avaliação nutricional foi realizada através da Avaliação Subjetiva Global Produzida pelo próprio Paciente (ASG-PPP). Além disso, o questionário EORTC QLQ-C15-PAL foi utilizado para avaliar a Qualidade de Vida. ***Resultados:*** Dos 70 pacientes, 58,6% (n=41) eram do sexo masculino, com idade entre 31 e 101 anos. Os tumores mais frequentes foram cabeça e pescoço (18,6%; n=13). A prevalência de desnutrição foi de 87,2% (n=61). Em relação à via alimentar, 84,3% (n=59) receberam alimentação por via oral e 15,7% (n=11), alimentação por sonda. O escore médio para o domínio Qualidade de Vida Global foi de 66,6, independentemente da via de alimentação. Pacientes desnutridos apresentaram maior escore nos domínios Função Física (34,9 ± 30; p=0,005) e Dispneia (20,7 ± 29,9; p=0,02). A alimentação por sonda foi associada a uma maior frequência de náusea (39,3 ± 35,9; p=0,014). ***Conclusões:*** Foi observada elevada frequência de desnutrição (87,2%) e baixa frequência de pacientes alimentados via sonda (15,7%). O estado nutricional e a alimentação por sonda não foram associados à Qualidade de Vida Global dos pacientes com câncer em cuidados paliativos. No entanto, a desnutrição foi associada à diminuição da função física e dispneia, enquanto a alimentação por sonda foi associada a uma frequência de náusea.

**Palavras-chave:** Cuidados paliativos; Oncologia; Terapia nutricional; Alimentação por sonda; Qualidade de vida.





## INTRODUCTION

Nutrition is an important tool in palliative care, since it promotes patient comfort and quality of life. Gastrointestinal discomforts and comorbidities should be controlled, as well as providing pleasure, preservation of self-esteem, independence, emotional comfort and greater participation with family members. Thus it helps way in the physical, psychological and social aspects.[1,2]

Tube feeding involves psychosocial factors such as physical discomfort, increasing the risk of bleeding, diarrhea, constipation, bronchoaspiration, refeeding syndrome and deprivation of sensorial characteristics of taste, texture, visualization of food and contact with family.[3-5] On the other hand, the offer of small amounts craved by patients increases their well-being, dignity and autonomy, improving the quality of life.[2,6,7]

The disease itself, the continuity of some medications, the decrease of food intake, the metabolic and physiological changes, eventually lead the patient to cachexia. This may have a psychosocial impact on the patient and their relatives, bringing them intense anxiety. This situation disrupts the structure of daily life, causing social and existential issues in the individual and many other challenges, due to distress in the patient and family environment, considering of course that food aversion is directly connected to death2,8,9 and decline in the quality of life.[8,10]

In addition, the symptoms related to gastrointestinal tract issues are more intense at this stage of disease resulting in impaired food intake. So health professionals often indicate tube feeding, analyzing if the benefits would be greater than the discomfort and complications. The indication of tube feeding at this stage makes it difficult to decide, since few studies in the area deal with this relationship and investigate the real benefits of tube feeding in these patients.[8]

The benefits of this therapy must be discussed in patients with illness in advanced stages mainly because this therapy could be aggressive and potentially negative. In fact, tube feeding often involves high costs and stressful experience. Moreover, a patient who could be forced to feed when he is without appetite may have several unpleasant symptoms such as nausea and abdominal pain.[2]

The use of tube feeding is justified if the care planning to maximize comfort and quality of life during the evolution of the disease respects the patient's and family's will, in a safe and consensual way.[2,7,8] In this sense, this study aimed to evaluate the impact of the nutritional status and the tube feeding therapy in the quality of life of oncologic patients attending a palliative care program.

## METHODS

A cross-sectional study was performed with oncologic patients in the "Palliative Care Program" (PCP) at the Oncologic University Hospital in Uberlândia, Minas Gerais state, Brazil.

### Subjects

The population included patients registered in the Palliative Care Program (n=92). The criteria of inclusion were both sexes, aged over than18, being currently registered in the program, capable to answer the questionnaire. According to this criteria, 22 patients were excluded, resulting in 70 patients analyzed in this study.

### Data Collection

The data was collected between July and November 2016, after being approved by the Ethics in Research Committee of Universidade Federal de Uberlândia, registered with CAAE n. 54864316.8.0000.5152. The patients were approached at the moment of their daily visit by the health team, and the questionnaire was answeredeither in the patient's home or at the palliative care ambulatory.

### Measures

Sociodemographic, clinical variables and the route feeding were collected using a structured questionnaire. For the nutritional diagnosis, the Patient-Generated Subjective Global Assessment (PG-SGA) was essentially performed, directly designed for the oncologic population. Height and weight were measured according to the World Health Organization (WHO) standards, the Body Mass Index (BMI) was estimated, and the adults and elderly were classified.[11]





The European Organization for Research and Treatment of Cancer (EORTC) questionnaire QLQ-C15-PAL, a validated and specific instrument for oncological populations in palliative care[12] was used for the evaluation of quality of life. The questionnaire consists of 15 questions, including a Physical Functioning scale, an Emotional Functioning scale, and seven symptom-related scales (Fatigue, Pain, Nausea, Dyspnea, Insomnia, Loss of Appetite and Constipation), as well as a question about the Global Quality of Life. Patients ranked each question on a Likert scale ranging from 1 (no) to 4 (very), except for the Global Quality of Life question, originally scored from 1 (very poor) to 7 (excellent). The final scores of each domain were estimated according to the EORTC QLQ-C15 PAL criteria by Groenvold,[12] and the mean and median scores of each domain were then calculated.

### Statistical Analysis

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) (version 20.0, Chicago, IL) using 95% confidence intervals (95% CI). The distribution of variables was analyzed by Kolmogorov-Smirnov test. Since all quality of life variables had the normality and assumption violated, the Mann-Whitney test was used to estimate the differences between scores of EORTC C15-PAL on quality of life domains and the nutritional status (according to PG-SGA), or to compare with dietary route of administration.

## RESULTS

Among 70 oncologic patients, 58.6% (41) were male. Regarding marital status, 55.7% (39) were single, widowed or divorced, and in 67.7% (47) of patients, the primary caregiver was a member of the family (table 1). For 68.2% (48), the time of enrollment in the Palliative Care Program was less than 6 months, and 48.6% (34) were diagnosed with cancer for more than 2 years. Regarding socioeconomic conditions, 55.4% (38) had a family income of 1 to 3 minimum wages (R$) and an average of 3.1 ± 1.3. The head and neck cancer was the most frequent, with18.6% (13), followed by the gynecological tumors - 11.4% (8), and prostate and lung - 8.6% (6). The frequency of comorbidities was 41.4% (29), being 62.1% with hypertension and 17.2% with diabetes mellitus. A high frequency of radiotherapy was observed (72.9%), and 61.4% of the participants required hospitalization.

**Table 1.** Demographic and clinical characteristics of cancer patients in palliative care. Uberlândia, Minas Gerais state, 2016.

| Variables | % (n) |
|---|---|
| **Sex** | |
| Male | 58.6 (41) |
| Female | 41.4 (29) |
| **Age Groups (years)** | |
| < 55 | 22.9 (16) |
| 56 – 65 | 21.4 (15) |
| 66 – 75 | 27.1 (19) |
| > 76 | 28.6 (20) |
| **Family Income (minimum wages[I])** | |
| ≤ 1 | 3.1 (2) |
| 1 – 3 | 55.4 (36) |
| >3 | 41.5 (27) |
| **Times of Registry at PCP[II]** | |
| < 6 months | 68.2 (45) |
| 6 – 12 months | 10.6 (7) |
| > 12 months | 21.2 (14) |
| **Comorbidities** | |
| With Comorbidities | 41.4 (29) |
| Diabetes Mellitus | 17.2 (5) |
| Arterial Hypertension | 62.1 (18) |
| Diabetes Mellitus + Arterial Hypertension | 20.7 (6) |
| **Time of Diagnosis** | |
| 1 – 6 months | 15.7 (11) |
| 7 – 11 months | 14.3 (10) |
| 1 – 2 years | 21.4 (15) |
| > 2 years | 48.6 (34) |
| **Placement of Tumor** | |
| Head and Neck | 18.6 (13) |
| Gynecological | 11.4 (8) |
| Prostate | 8.6 (6) |
| Lungs | 8.6 (6) |
| Others | 52.8 (37) |
| **Treatment** | |
| Radiotherapy | 72.9 (51) |
| Chemotherapy | 65.7 (46) |
| Surgery | 55.7 (39) |

[I] Minimum Wage: R$ 880,00; [II]PCP: Palliative Care Program.





Malnutrition ranged from 25% (17) to 87.2% (61), depending on the method used, being the lowest value by the BMI, and the highest proportion by the PG-SGA, as expected. Concerning nutritional therapy, 84.3% (59) were receiving oral feeding (associated or not with oral supplementation), while 15.7% (11) had tube feeding, either exclusively by nasal--enteral tube, gastrostomy or jejunostomy, or associated with oral nutrition (table 2).

**Table 2.** Anthropometric and nutritional characteristics of cancer patients in palliative care. Uberlândia, Minas Gerais state, 2017.

| Variables | % (n) Mean±SD |
|---|---|
| **Weight (kg)** | 58.3 ±12.0 |
| **Height(m)** | 1.62 ±0.08 |
| **BMI (kg/m²)** | |
| Slimness | 25.0 (17) |
| Eutrophic | 60.3 (41) |
| Overweight and Obesity | 14.7 (10) |
| **PG-SGA** | |
| A - Well Nourished | 12.8 (9) |
| B - Moderated Malnourishment | 62.9 (44) |
| C - Severe Malnourishment | 24.3 (17) |
| **Route of Administration of Diet** | |
| Exclusively Orally | 40.0 (28) |
| Orally+ supplement by mouth | 44.3 (31) |
| Exclusively Enteral | 11.4 (8) |
| Enteral +Orally | 4.3 (3) |
| **Time of supplement usage OA (days)** | 90.0[a] |
| **Time of use of tube feeding (days)** | 30.0[a] |

BMI: body mass index; PG-SGA: Patient-Generated Subjective Global Assessment; OA: Orally Administered. SD: Standard Deviation. [a]Values referring to the median.

The mean score of each domain that composes the Quality of Life (EORTC QLQ-C15-PAL) questionnaire is shown in table 3.

**Table 3.** Mean and median domains of the questionnaire EORTC QLQ-C15 PAL. Uberlândia, Minas Gerais state, 2016.

| Variables | Mean | DP | Median | Min | Max |
|---|---|---|---|---|---|
| Global Quality of Life | 66.6 | 26.9 | 66.6 | 0 | 100 |
| Physical Functioning | 31.4 | 29.6 | 22.0 | 0 | 100 |
| Emotional Functioning | 40.9 | 34.2 | 33.3 | 0 | 100 |
| Fatigue | 36.1 | 28.0 | 33.3 | 0 | 100 |
| Nausea | 20.9 | 32.1 | 00.0 | 0 | 100 |
| Pain | 35.7 | 35.6 | 25.0 | 0 | 100 |
| Dyspnea | 19.0 | 28.6 | 00.0 | 0 | 100 |
| Insomnia | 27.6 | 35.8 | 00.0 | 0 | 100 |
| Appetite | 32.3 | 41.3 | 00.0 | 0 | 100 |
| Constipation | 30.4 | 37.9 | 00.0 | 0 | 100 |

SD: Standard Deviation.

The Global Quality of Life domain received an average score of 66.6 (on a scale ranging from 0 to 100) and more than half of the patients obtained a median score of zero for the domains Nausea, Dyspnea, Insomnia, Appetite and Constipation. The malnutrition group showed a higher score for the Physical Functioning domains and Dyspnea when compared to those considered well-nourished (table 4).

**Table 4.** Comparison between the medians of EORTC C15-PAL quality of life domains with the classification of nutritional status according to PG-SGA. Uberlândia, Minas Gerais state, 2016.

| Domains | PG-SGA scores Median (Minimum – Maximum) Mean (±Standard-Deviation) | | *p*-value* |
|---|---|---|---|
| | Eutrophic | Malnourished | |
| Global Quality of Life | 83.33 (50-100)<br>81.3 (±17.5) | 66.66 (0-100)<br>64.4 (±27.4) | 0,070 |
| Physical Functioning | 11.1 (0-22)<br>7.4 (±7.8) | 33.3 (0-100)<br>34.9 (±30.0) | 0,005* |
| Emotional Functioning | 16.6 (0-66)<br>20.3 (±21.6) | 33.3 (0-100)<br>43.9 (±34.8) | 0,059 |
| Fatigue | 16.6 (0-66)<br>25.9 (±20.6) | 33.3 (0-100)<br>37.7 (±28.8) | 0,224 |
| Nausea | 00.0 (0-100)<br>11.1 (±33.3) | 00.0 (0-100)<br>22.4 (±32.0) | 0,122 |
| Pain | 00.0 (0-100)<br>18.5 (±32.7) | 33.3 (0-100)<br>38.2 (±35.6) | 0,095 |

**Mann-Whitney U test.* PG-SGA: Patient-Generated Subjective Global Assessment.





Table 4 continued

| Domains | PG-SGA scores Median (Minimum – Maximum) Mean (±Standard-Deviation) | | *p*-value* |
|---|---|---|---|
| | Eutrophic | Malnourished | |
| Dyspnea | 00.0 (0-33)<br>7.4 (±14.6) | 00.0 (0-100)<br>20.7 (±29.9) | 0,022* |
| Insomnia | 00.0 (0-100)<br>14.8 (±33.7) | 33.3 (0-100)<br>29.5 (±36.0) | 0,152 |
| Appetite | 00.0 (0-100)<br>11.1 (±35.5) | 33.3 (0-100)<br>35.5 (±41.6) | 0,051 |
| Constipation | 00.0 (0-100)<br>22.2 (±31.6) | 00.0 (0-100)<br>31.6 (±38.6) | 0,580 |

**Mann-Whitney U test.* PG-SGA: Patient-Generated Subjective Global Assessment.

Finally, table 5 showed that tube feeding was associated with a higher frequency of nausea (p=0.014), but not with the global quality of life.

**Table 5.** Comparison between the medians of the quality of life domains of the EORTC-C15-PAL scale with dietary route of administration. Uberlândia, Minas Gerais state, 2016.

| Domains | Enteral Nutrition* | | | Oral Nutrition | | |
|---|---|---|---|---|---|---|
| | Yes (11) | No (59) | *p*-value* | Exclusive (28) | Oral Supplement (31) | *p*-value* |
| | Median (Minimum – Maximum) Mean (±Standard-Deviation) | | | | | |
| Global Quality of Life | 66.6 (16.6-100)<br>63.6 (±27.7) | 66.6 (0-100)<br>67.2 (±26.9) | 0.741 | 66.6 (0-100)<br>66.6 (±27.9) | 66.6 (0-100)<br>67.7 (±26.5) | 0.858 |
| Physical Functioning | 33.3 (0-100)<br>46.4 (±41.8) | 22.2 (0-100)<br>28.6 (±26.2) | 0.253 | 16.6 (0-55)<br>21.8 (±36.8) | 33.3 (0-100)<br>34.7 (±30.9) | 0.170 |
| Emotional Functioning | 33.3 (0-100)<br>43.9 (±29.1) | 33.3 (0-100)<br>40.3 (±35.3) | 0.572 | 41.6 (0-100)<br>45.2 (±36.8) | 33.3 (0-100)<br>36.0 (±33.9) | 0.363 |
| Fatigue | 33.3 (0-100)<br>39.3 (±30.9) | 33.3 (0-100)<br>35.5 (±27.7) | 0.817 | 33 (0-83)<br>35.7 (±27.1) | 33.3 (0-100)<br>35.4 (±28.7) | 0.864 |
| Nausea | 33.3 (0-100)<br>39.3 (±35.9) | 00.0 (0-100)<br>17.5 (±30.5) | 0.014* | 00.0 (0-100)<br>19.0 (±33.2) | 33.3 (0-100)<br>16.1 (±28.3) | 0.905 |
| Pain | 33.3 (0-100)<br>40.9 (±34.7) | 16.6 (0-100)<br>34.7 (±35.7) | 0.632 | 08.3 (0-100)<br>28.5 (±37.0) | 33.3 (0-83)<br>40.3 (±34.0) | 0.076 |
| Dyspnea | 00.0 (0-100)<br>15.5 (±17.4) | 00.0 (0-100)<br>19.7 (±30.3) | 0.941 | 00.0 (0-100)<br>11.9 (±24.3) | 00.0 (0-33)<br>26.8 (±33.7) | 0.052 |
| Insomnia | 33.3 (0-100)<br>45.4 (±42.8) | 00.0 (0-100)<br>24.2 (±33.8) | 0.107 | 00.0 (0-100)<br>26.1 (±35.5) | 33.3 (0-100)<br>22.5 (±32.6) | 0.709 |
| Appetite | 00.0 (0-100)<br>33.3 (±42.1) | 00.0 (0-100)<br>32.2 (±41.5) | 0.986 | 00.0 (0-100)<br>26.1 (±40.9) | 00.0 (0-100)<br>37.6 (±41.9) | 0.203 |

**p-values* < *0,05* indicate statistical significance. *Mann-Whitney U test.*

Table 5 continued

| Domains | Enteral Nutrition* | | | Oral Nutrition | | |
|---|---|---|---|---|---|---|
| | Yes (11) | No (59) | *p*-value* | Exclusive (28) | Oral Supplement (31) | *p*-value* |
| | Median (Minimum – Maximum)<br>Mean (±Standard-Deviation) | | | | | |
| Constipation | 33.3 (0-100)<br>33.3 (±39.4) | 00.0 (0-100)<br>29.4 (±38.0) | 0.726 | 00.0 (0-100)<br>32.1 (±43.0) | 33.3 (0-100)<br>27.9 (±33.4) | 0.804 |

**p-values* < *0,05* indicate statistical significance. *Mann-Whitney U test.*

## DISCUSSION

In this study, the frequency of malnutrition was high (87.2%). Malnourished patients had a higher score (worse prognosis) for the Physical Function domains and Dyspnea. The tube feeding was associated with a higher frequency of nausea.

The high prevalence of malnutrition is reported in cancer patients[13-15] including palliative care.[5,16] It was observed that PG-SGA would be the most adequate instrument to evaluate the nutritional status than the BMI. This can be explained by the fact that the PG-SGA evaluates several aspects of the patient as signs and symptoms, metabolic stress, functional capacity and physical examination, and not just anthropometry, measured by BMI. Moreover, the evaluation performed by BMI may be compromised because of changes in inflammatory mediators that culminate in the expansion of extracellular fluid, leading to water retention, masking actual weight and consequently nutritional status.[17]

Nutritional status was associated with some domains of quality of life. Malnourished patients presented a median for the Physical Functioning and Dyspnea domains significantly higher than patients classified as well-nourished according to the PG-SGA, which shows physical and respiratory worsening. These values were expected due to the great loss of muscular mass in oncology patients.[18]

Anorexia is expected with the approach of death, and brings anguish to caregivers and professionals, inducing the feeling that death is accelerated by inappetence. This is a possible cause of frequent use of enteral nutrition (EN) in end-of-life patients as a means of alleviating the distress of family members and caregivers.[7,8] It is crucial to understand autonomy, respecting the decisions and desires of patients as far as they can answer for themselves.[10]

The high number of patients who were orally fed (84.3%) may be justified by the professional's ability and respect for the patient's decision not to use tube feeding. Enteral nutrition is most commonly found in patients with neurological deficits, when the family members became responsible for the decisions of possible procedures.





The National Consensus on Nutrition Oncology, recently published in Brazil,[19] reports that patients in palliative care do not benefit from indication of EN. The guideline of the European Society for Clinical Nutrition and Metabolism (ESPEN)[6] also describes that cancer patients with rapidly progressive disease are less likely to benefit from EN. This fact is attested by studies that show that EN has no consistent effect on patients' survival and quality of life.[20,21] In the present study, it is possible to observe that the recommendation of the guidelines has been applied in clinical practice, since only 15.7% of the patients were using EN, without improvement in the quality of life.

Patients using tube feeding showed significantly higher median for nausea scores. It is known that therapy can lead to greater complications and gastrointestinal alterations, including nausea, caused by the administration of a volume greater than that tolerated by the patient and inadequate infusion, since it is administered at home by the caregivers, who often have difficulty to deal with tube feeding. Similar result was found in the study by Brotherton[3], in which the quality of life of patients in ENT presented lower scores when compared to the control group. The main factors highlighted by the authors that probably affected the quality of life included symptoms such as nausea, vomiting, diarrhea and fatigue, as well as disorders related to body image and loss of autonomy.[3] On the other hand, studies suggest that home ENT can ensure the quality of life of the patient and humanized practices.[22]

The comparison between exclusive oral feeding and oral feeding plus supplementation showed no difference in the domains of quality of life, differently from the literature, where it is suggested that oral supplementation may improve the quality of life of oncologic patients.[23] Sample variability, study design, and time of diagnosis may explain the differences found in the results.

Observing the means of each EORTC QLQ-C15-PAL questionnaire score and the mean scores of other studies, we found a trend towards better Global Quality of Life and better control of Pain, Fatigue, Constipation and Lack of Appetite. Leppert[24] and Lee[25] found a mean of Global Quality of Life of 37.4 and 16.7, respectively, values lower than the one found in this study (66.6). The same occurs in the domains Constipation and Pain, in which the mean in this study was 30.4 and 35.7, respectively; in the study by Lee[25] the mean found for Constipation was 66.7 and, for the Pain domain, these studies presented a mean of 76.4.[24,25] This result demonstrates that the effective control of pain, constipation and other frequent symptoms can provide a better quality of life, evidenced by the difference in the mean of the Global Quality of Life score between the studies, where patients who reported lower intensity symptoms presented higher scores in these domains.

Finally, this study had some limitations regarding the population, due to the low number of patients enrolled in the Palliative Care Program and their short time in palliative care.

In addition, among the patients excluded from the sample (23.9%), some used tube feeding but were not included in this study due to lowering of consciousness level, cognitive alterations, somnolence and delirium, common and expected clinical signs in patients in the end of life.[2]

## CONCLUSIONS

Malnutrition showed a high frequency (87.2%), and a low frequency of tube feeding (15.7%). Nutritional status and tube feeding were not associated with the Global Quality of Life of these cancer patients in palliative care. However, malnutrition was associated with worse physical function and dyspnea (worse prognosis), while tube feeding was associated with a higher frequency of nausea.

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**Contributors**

Cruz FCS participated in the design of the study, in the collection and analysis of data and writing the final version of the article. Borges FM and da Silva EHE participated in the collection and elaboration of the database. Pena GG participated in the design of the study, the data analysis and review of the final version.

Conflict of Interest: The authors declare no conflict of interest.

Received: November 6, 2018
Reviewed: January 16, 2019
Accepted: February 1, 2019