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Subjective global assessment and prealbumin levels of esophageal cancer patients undergoing concurrent chemoradiotherapy

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Abstract

Aims: **To evaluate the nutritional status of patients undergoing chemoradiotherapy for esophageal cancer using subjective global assessment (SGA) and association of prealbumin levels to nutritional status.**

Methods: **A prospective study was performed on 154 patients with esophageal cancer who were treated with concurrent chemoradiotherapy at center of radiation oncology in Huai'an First People's Hospital from January 2012 to May 2013. The patients' nutritional status after receiving concurrent chemoradiotherapy were evaluated using SGA tool. Serum total protein, prealbumin, albumin and other biochemical nutrition parameters including triglyceride, total cholesterol, cholesterol and glucose were determined before beginning and after the end of radiotherapy.**

Results: **Malnutrition developed in 129 (83.8%) patients. According to SGA results, 16.2%, 66.2%, and17.6% of patients were classified as A, B, or C, respectively. Loss of subcutaneous fat or muscle wasting (odds ratio [OR] 11.522); increased metabolic demand/ stress (OR 8.637); ankle, sacral edema, or ascites (OR 3.229) and weight loss ≥5% (OR 2.294) were significantly associated with malnutrition (SGA B or C; $p < 0.001$). Prealbumin level after the end of radiotherapy was significantly lower in patients with malnutrition (17 ±5 g/ dl vs. 21 ±5 g/dl, $p = 0.005$), but it showed no difference before beginning radiotherapy (24 ±4 g/dl vs. 22 ±5 g/ dl, $p > 0.05$). On the other hand, there was no significant difference in term of other nutrition parameters whether before beginning or after the end of radiotherapy ($p > 0.05$).**

Conclusions: **The prevalence of malnutrition was high in esophageal cancer patients undergoing concurrent chemoradiotherapy. The results serve as a basis for implementation of nutrition intervention to patients being treated at radiotherapy departments. Prealbumin**

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VALORACIÓN GLOBAL SUBJETIVA Y NIVELES DE PREALBÚMINA DE PACIENTES CON CÁNCER ESOFÁGICO SOMETIDOS A QUIMIORRADIOTERAPIA CONCURRENTE

Resumen

Objetivos: **Evaluar el estado nutricional de los pacientes sometidos a quimioterapia para cáncer esofagico usando subjetiva evaluación mundial(SGA) y Asociación de prealbumina a niveles de estado nutricional.**

Métodos: **Se realiza un estudio prospectivo en 154 pacientes con cáncer esofágico que fueron tratados con quimiorradioterapia concurrente en centro de Oncología de radiación en Huai 'an First People' s Hospital desde enero de 2012 a mayo de 2013. El estado nutricional de los pacientes después de recibir quimiorradioterapia concurrente fueron evaluados utilizando la herramienta de SGA. Albúmina, prealbúmina, proteína sérica total, nutrición y otros parámetros bioquímicos, incluyendo triglicéridos, colesterol total, colesterol y glucosa fueron determinados antes de empezar y después del final de la radioterapia.**

Resultados: **La desnutrición desarrollada en 129 (83,8%) pacientes. Según SGA resultados, 16,2%, 66,2%, y 17,6% de los pacientes fueron clasificados como a, B, o C, respectivamente. La pérdida de grasa subcutánea o atrofia muscular (odds ratio [OR] 11.522); demanda metabolica creciente / estrés (o 8.637); tobillo edema sacro, o ascitis (o -) y la perdida de peso ≥ 5% (o 3) estuvieron significativamente asociados con la malnutrición (SGA B o C; $p < 0,001$). El nivel de prealbúmina después del final de la radioterapia fue significativamente menor en los pacientes con desnutrición (17 ± 5 g / dl vs. 21 ± 5 g / dl, $p = 0,005$), pero no mostró diferencia antes de comenzar la radioterapia (24 ± 4 g / dl vs. 22 ± 5 g / dl, $p > 0,05$). Por otro lado, no hubo diferencia significativa en el plazo de otros parámetros si la nutrición fue antes de comenzar o después del final de la radioterapia ($p > 0,05$).**

Conclusiones: **La prevalencia de la malnutrición era alta en cáncer de esófago en pacientes sometidos a quimiorradioterapia concurrente. Losresultados sirven de base para la aplicación de la intervención en materia de nutrición para pacientes en tratamiento en los servicios de radioterapia. La prealbumina mostró relación con SGA a valorar y debe ser considerado como un biomar-**

showed relation with SGA rating and should be considered as a sensitive nutritional biomarker for evaluating nutritional status of esophageal cancer patients undergoing concurrent chemoradiotherapy.

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Key words: *Malnutrition. Nutrition assessment. Subjective global assessment. chemoradiotherapy. prealbumin.*

cador sensible nutricional para evaluar el estado nutricional de cáncer esofágico en pacientes sometidos a quimiorradioterapia concurrente.

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Palabras clave: *Malnutrición. Evaluación nutricional. Evaluación subjetiva mundial. Quimiorradioterapia. Prealbúmina.*

Introduction

Esophageal cancer is the eighth most common cancer worldwide. It is a highly lethal disease, causing more than 400,000 deaths per year. The incidence of esophageal cancer is rapidly rising. In the People's Republic of China, esophageal cancer is the fourth most common cause of mortality, with 16.77 deaths per 100,000 in 2009.

Malnutrition occurs frequently in patients with cancer. It affects cancer patients during and after radiotherapy ,chemotherapy, or surgical treatment [1]. The serious consequences of malnutrition may include an increase risk of toxicity, infection, as well as decreased treatment response, compliance, quality of life[2].Patients with esophageal cancer are among those cancer patients in whom malnutrition is the most common. Given the importance of nutritional status, screening patients at risk for malnutrition and providing a nutrition support program is of great concern. The acute reactions as results of undergoing concurrent chemoradiotherapy are associated with diverse gastrointestinal symptoms and decreased food intake, resulting in deterioration of the patient's nutritional status. Despite the frequent occurrence of nutritionally related side effects, a nutritional assessment of patients with cancer receiving radiotherapy is not routine practice in clinical departments. There has been no study as of yet investigating the prevalence of malnutrition during radiotherapy for esophageal cancer in China. This prospective study was performed to evaluate the nutritional status using SGA in patients undergoing radiotherapy for esophageal cancer.

Protein-calorie malnutrition is observed in approximately 80% of the patients with esophageal cancer [3,4].Serum proteins provide indirect information about the visceral protein levels. Serum albumin used to be a surrogate marker of nutritional status; however, its half-life of 21 days makes it only minimally valuable. In conditions in which malnutrition develops in a short time, albumin is not a clinically relevant nutritional marker [5,6].Another aim of this prospective study was to determine a sensitive biomarker in patients undergoing radiotherapy for esophageal cancer.

Material and Methods

Patients

Between January 2012 and May 2013, 154 patients with esophageal cancer were enrolled. These patients received chemoradiotherapy at center of radiation oncology in Huai'an First People's Hospital, Nanjing Medical University. The criterion for enrollment was histological evidence of invasive squamous cell carcinoma of the thoracic esophagus, exclusive of esophagogastric junction. Only patients with tumors of clinical stage T1N1 or T2-3N0-1 and no clinical evidence of metastatic spread, according to the International Union against Cancer (UICC) tumor–node–metastasis(TNM) classification(Preoperative Chemoradiotherapy for Esophageal or Junctional Cancer), were enrolled. Eligible patients were 18 to70 years of age, had an Eastern Cooperative Oncology Group (EOCG) performance status score less than or equal to 2. In addition, adequate hematologic, renal, hepatic, and pulmonary function, as well as no history of other cancer or previous radiotherapy or chemotherapy was required. The study protocol was approved by the local ethics committee. All the patients gave informed written consent.

The nutritional status of each patient was assessed after the end of radiotherapy, and was determined using subjective global assessment tool.

Blood samples

Blood samples were taken from all patients for laboratory examinations such as complete blood count, serum total protein, albumin, prealbumin, glucose, and total lipid profile before beginning the treatment and after the end of the treatment. Prealbumin levels were determined by nephelometric method.

Techniques of treatment

Concurrent chemoradiotherapy

The daily fractional dose of radiation was 2Gy given five days a week; thus, the Patients received a to-

tal radiation dose of 56-60Gy in 28-30 fractions using three-dimensional conformal radiotherapy technique (3D-CRT). The maximal allowable overall dose to the spinal cord was 45Gy. Twenty seven percent of normal lung tissue was allowed to receive no more than 20Gy. Dose as high as 40Gy could be given to less than 40-50 percent of the heart.

All patients received concurrent chemotherapy consisting of two cycles cisplatin and 5-fluorouracil, which were administered on the first week and fourth week during the radiotherapy course. Fluorouracil (500 mg/m^2) was administered as continuous intravenous infusion on d1-5 and d29-33.Cisplatin (30 mg/m^2) was given on d1-3 and d29-31.

If Grade 3/4 myloesuppression, or body temperature of 38.0º C or more and any other life-threatening toxicities were observed , administration of chemoradiotherapy was discontinued until recovery from toxicity.

Toxicity assessment

Acute toxicity were graded according to the RTOG criteria [7]. Severe radiotherapy-related toxicities were defined as grade 3 or 4 radiotherapy-related toxicities.

Statistical analysis

Statistical analysis was performed using SPSS 18.0 software(SPSS Inc., Chicago, IL, USA). Continuous variables with normal distribution were presented as mean ± SD. The median value was used where normal distribution was absent. Qualitative variables were given as percent. Statistical analysis for the parametric variables was performed using the Student's t-test between two groups. The Mann-Whitney U test was used to compare nonparametric variables between two groups. The chi-square test and Fisher exact test were used to compare qualitative data between two groups. To identify independent risk factors for malnutrition, binary logistic regression analysis was performed. A level of $p<0.05$ was considered to be statistically significant.

Results

Table I is a comparison of nutritional characteristics of subjects according to SGA for the two groups(patients without malnutrition and patients with malnutrition).Patients in both groups were of similar age (age[years] <60:48.0% VS.43.4%,age≥60:52.0% VS. 56.6) and were mainly male (80.0% VS. 82.9%).The clinical stages (UICC-TNM 1997 Edition) were II a for 27 patients, II b for 60 patients and III for 67 patients. On the other hand, when relating to the demographic parameters including age, gender, it showed no significant difference between the two groups ($P > 0.05$). Malnutrition developed in 129 (83.8%) patients after the end of radiotherapy. According to SGA, 25 (16.2%), 102 (66.2%), and 27 (17.6%) patients were SGA A, SGA B, and SGA C, respectively. Loss of subcutaneous fat or muscle wasting strongly was associated with the development of malnutrition (OR 11.522, $P< 0.001$). Metabolic demand/stress was the next most strongly contributing factor (OR 8.637, $P < 0.001$). Patients with ankle, sacral edema, or ascites upon physical examination were also at a higher risk of being malnourished (OR 3.229,$P< 0.001$). Additionally, patients with ≥5% weight loss in the previous 6 months were also more likely than other patients to be malnourished (OR 2.294,$P< 0.001$).

Comparison of biochemical nutrition parameters in patients with and patients without malnutrition before beginning and after the end of radiotherapy are summarized in Table II and Table III respectively. Level of prealbumin after the end of radiotherapy was significantly lower in patients with malnutrition than in those without malnutrition(P=0.005), while no statistical significance was observed before beginning radiotherapy(P=0.875). In term of other biochemical nutrition parameters including total protein, albumin, total cholesterol, triglyceride, and glucose, there was no significant difference between the two groups whether before beginning radiotherapy or after the end of radiotherapy($P > 0.05$).

Figure 1 exhibits the comparison of treatment related severe toxicities in patients with and without malnutrition. No treatment-induced death occurred. The main observed non-hematologic severe toxicities were dysphagia, anorexia and nausea/vomiting. Overall, patients with malnutrition developed more treatment-related toxicities than those without malnutrition. Patients with poor nutrition status presented severe dysphagia(20.0% VS. 78.3%,P<0.05), anorexia (8.0% VS. 17.0%,P=0.02), severe nausea/vomiting (3.3% VS. 18.1%,P<0.001)and severe hematologic toxicities (32.0% VS. 56.6%,P<0.001) more frequently than those in a good nutrition status.

Discussion and Conclusions

Malnutrition is a potentially serious condition often comorbid with cancer and its treatment [2]. An estimated incidence of malnutrition in cancer patients has been reported to range from approximately 10% to 80% and malnutrition itself was one of the reasons for death in up to 20% of cancer patients [2]. In an observational cross-sectional descriptive study, malnutrition was found in two thirds of the 997 cancer patients [8]. In a study performed by Jon Cacicedo et al., malnutrition was found in 65.7% of the oncologic patients undergoing radiotherapy [9].It was also observed that the patients with digestive cancer had the highest presence of malnutrition [8]. In patients with esophageal cancer, weight loss is common and a frequent cause of patient

Table I
nutritional characteristics of subjects according to subjective global assessment category

Characteristic	*Patients without malnutrition (SGA A,n=25)*	*Patients with malnutrition (SGA B and C,n=129)*	*P*
Age (year)			0.120
<60	12 (48.0)	56 (43.4)	
≥60	13 (52.0)	73 (56.6)	
Sex			0.227
Male (%)	20 (80.0)	107 (82.9)	
Female (%)	5 (20.0)	22 (17.1)	
Percent weight loss in past six moths (%)			<0.001
<5	20 (80.0)	55 (42.6)	
≥5	5 (20.0)	74 (57.4)	
Weight change in previous two weeks			<0.001
Increase or no change	20 (80.0)	67 (51.9)	
Decrease	5 (20.0)	62 (48.1)	
Dietary intake change			<0.001
No	19 (76.0)	62 (48.1)	
Yes	6 (24.0)	67 (51.9)	
Gastrointestinal symptoms persisting more than two weeks			<0.001
No	19 (76.0)	78 (60.5)	
Yes	6 (24.0)	51 (39.5)	
Functional capacity			<0.001
No	17 (68.0)	64 (49.6)	
Yes	8 (32.0)	65 (50.4)	
Metabolic demand/stress			<0.001
No or low	23 (92.0)	70 (54.3)	
Moderate or high	2 (8.0)	59 (45.7)	
Loss of subcutaneous fat			<0.001
No	21 (84.0)	33 (25.6)	
Yes	4 (16.0)	96 (74.4)	
Muscle wasting			<0.001
No	21 (84.0)	50 (38.8)	
Yes	4 (16.0)	79 (61.2)	
Ankle edema			<0.001
Yes	2 (8.0)	23 (17.8)	
No	23 (92.0)	106 (82.2)	
SGA score after the end of radiotherapy		A: 25 (16.2%) B: 102 (66.2%) C: 27 (17.6%)	

concern. Prevalence of weight loss in esophageal cancer patients had been reported to range from 32% to 70% [10]. In our study, malnutrition was observed in 129 (83.8%) patients.

Malnutrition is associated with a higher risk of developing complications and with mortality, lengthening the hospital stay by up to 90%, thus increasing hospitalization costs by 35-75% [11]. It contributes to an increase risk of toxicity, infection, as well as decreased treatment response, compliance, quality of life, and ultimately patient survival [2]. Therefore, early identification of malnutrition in cancer patients and nutritional intervention may increase tolerance to cancer treatment and improve quality of life and prognosis. Although first described more than two decades ago, subjective global assessment is still a reliable tool

Table II
Comparison of biochemical nutrition parameters in patients with and patients without malnutrition before beginning radiotherapy

Parameter	*Patients without malnutrition*	*Patients with malnutrition*	*P*
Total protein (g/dl)	7.87 ±0.65	7.53 ±0.52	0.069
Albumin (g/dl)	4.70 ±0.35	4.41 ±0.38	0.068
Prealbumin (g/dl)	24 ±4	22 ±5	0.875
Total cholesterol (mg/dl)	201 ±49	220 ±40	0.547
Triglyceride (mg/dl)	126 (57–380)	120 (50–375)	0.633
Glucose (mg/dl)	99 (53–150)	95 (53–177)	0.734
Hemoglobin (g/dl)	16.3 ±2.0	15.5 ±1.9	0.858

Table III
Comparison of biochemical nutrition parameters in patients with and patients without malnutrition after the end of radiotherapy

Parameter	*Patients without malnutrition*	*Patients with malnutrition*	*P*
Total protein (g/dl)	7.30 ±0.67	7.02 ±0.47	0.064
Albumin (g/dl)	4.32 ±0.40	4.01 ±0.35	0.063
Prealbumin (g/dl)	21 ±5	17 ±5	0.005
Total cholesterol (mg/dl)	209 ±40	200 ±51	0.397
Triglyceride (mg/dl)	120 (59–390)	115 (47–386)	0.587
Glucose (mg/dl)	97 (55–147)	90 (54–168)	0.783
Hemoglobin (g/dl)	14.1 ±2.3	11.9 ±1.8	0.012

for assessing nutritional status of patients with cancer[2]. This assessment tool is simple, non-invasive, and inexpensive, consisting of a medical history and a physical examination. SGA classifies patients into three nutritional status groups: well nourished (SGA A), moderately malnourished (SGA B), and severely malnourished (SGA C). According to SGA, 83.8% of the patients enrolled in this study were malnourished (SGA B+SGA C). The finding related to the frequency of malnutrition in our study was similar to those regarding the prevalence of malnutrition in cancer patients mentioned in the first paragraph.

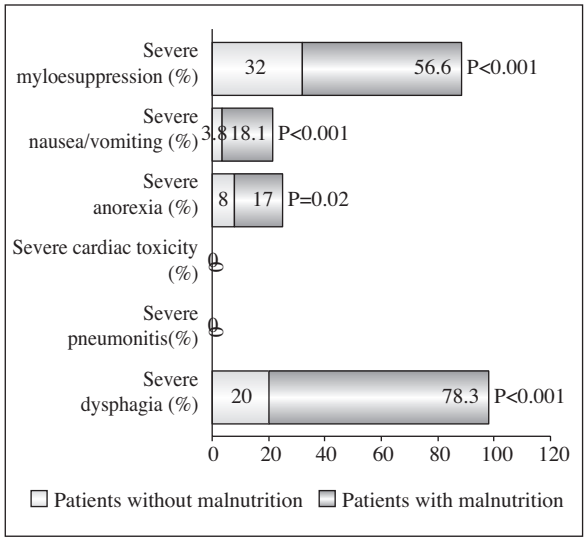

Fig. 1.—Comparison of treatment related toxicities in patients with and patients without malnutrition.

Protein-calorie malnutrition is observed in approximately 80% of the patients with esophageal cancer [3,4].Depressed serum proteins are thought to be associated with a greater incidence of morbidity and mortality in cancer patients. Several studies reported similar findings [12]. Serum proteins provide indirect information about the visceral protein levels. A decrease in protein levels indicates low hepatic synthesis and is generally associated with inadequate intake. Among the biochemical parameters used for assessing nutritional status, serum albumin, synthesized in liver, is one of the most widely used clinical indexes[13,14]. However, its long half-life(21 days) prevents nutritional changes from being reflected rapidly. The half-life of serum prealbumin is 2-3 days. And this protein is affected earlier by the acute alterations in protein balance [4,5,6]. Therefore, prealbumin is a more sensitive marker than albumin to assess the nutritional

status. A prospective study has proved that prealbumin is a sensitive biomarker to assess nutritional status of patients with head and neck cancer undergoing radiotherapy[15].Similarly, in our study, prealbumin level was significantly lower in patients with malnutrition than in those without malnutrition after the end of the radiotherapy, but no significant difference was observed before the beginning of radiotherapy. There was no significant difference between the two groups in term of albumin and other biochemical parameters including triglyceride, total cholesterol, cholesterol and glucose wether before the beginning or after the end of radiotherapy.

Most of the radiotherapy related toxicities are closely associated with nutritional problems[16]. Esophagitis is the primary acute toxicity during radiotherapy in patients with esophageal cancer. Patients with esophagitis have pain and difficulties in swallowing. In this study, nearly 68.8% of the 154 patients developed severe dysphagia. And more importantly, the incidence of severe dysphagia in the group with malnutrition was significantly higher than that in the group without malnutrition. The data from this study provided strong evidence to support that dysphagia was a contributing factor to malnutrition in patients with esophageal cancer. This finding was in accordance with the findings of a study conducted by Jiang N et al[10]. Concurrent chemoradiotherapy has remained the standard treatment for locally advanced esophageal cancer. It is well known that radiosensitization of chemoradiotherapy results in increased acute toxicities[9]. Nausea and vomiting, major side effects of combination of cisplatin and 5-fluorouracil, may contribute to weight loss in patients undergoing chemoradiotherapy. The occurrence rate of severe nausea/vomiting in patients with malnutrition was significantly higher than that in patients without malnutrition in this study. It was noteworthy that anorexia was another significant factor to malnutrition. In this study, severe anorexia was detected in 17% of the patients with malnutrition as compared with 8% of the patients without malnutrition. The incidences of severe anorexia in the two groups showed significant difference. Patients with loss of appetite had a higher risk of weight loss during radiotherapy [10]. With the development of 3D-CRT technique, the control of pneumonitis became possible for the radiation treatment of esophageal cancer. Accordingly, radiation pneumonitis was not occurred in the study.

In conclusion, this study identified the prevalence of malnutrition using the SGA tool in esophageal cancer patients treated with concurrent chemoradiotherapy. Malnutrition was a common complication in patients undergoing chemoradiotherapy for esophageal cancer. Prealbumin level showed relation with SGA rating and should be considered as a sensitive nutritional biomarker for evaluating nutritional status of esophageal cancer patients undergoing concurrent chemoradiotherapy. The results of this study serve as a basis for implementation of nutrition intervention to patients being treated at radiation oncology departments. In addition, the sample of this study was from a single hospital with a relatively small number of patients. A multicenter study will be needed in the future.

Author contribution

Conception/Design: Xinchen Sun, Peng Pan

Collection and/or assembly of data: Peng Pan, Guangzhou Tao

Data analysis and interpretation: Peng Pan, Guangzhou Tao

Manuscript writing: Peng Pan

Final approval of manuscript: Peng Pan , Xinchen Sun, Guangzhou Tao

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