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The Prevalence of Malnutrition in Oncology Patients in a Greek General Hospital. Evaluation Using Anthropometric and Laboratory Measurements

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Abstract

Background and Purpose: The incidence of malnutrition in oncology patients is high, and it depends on the type, location and stage of the tumor and on the treatment. In this empirical study, we aimed to evaluate the prevalence of malnutrition in adults with cancer in a Greek general hospital and to investigate the relationship between objective and subjective nutritional assessment of the patients.

Methods: We assessed the nutritional status of 88 oncology patients within 48 hours of admission, using the three nutrition screening tools Subjective Global Assessment (SGA), Nutritional Risk Screening 2002 (NRS 2002) and Malnutrition Screening Tool (MST). The degree of malnutrition was determined using anthropometric measurements and laboratory nutrition-related parameters.

Results: In this Greek hospital, the rate of malnutrition risk in patients with cancer varied, ranging from 35.3% to 45.5%, depending on the nutrition screening tool used. Men, elderly patients and patients with gastric cancer were demonstrated to be at higher risk of malnutrition. Malnourished patients showed significant weight loss, with anorexia being the main gastrointestinal symptom. The objective laboratory nutrition parameters did not always indicate nutritional deficiency, but the anthropometric measurements showed a decrease in these patients.

Conclusions: The problem of malnutrition among Greek oncology patients appears to be significant and there is a need for further efforts in its detection and management.

Key words: *Nutritional screening tools; oncology patients; malnutrition; epidemiological study*

Introduction

Malnutrition is a common problem in patients with cancer and weight loss may be the first symptom of the disease. It has been suggested that up to 20% of oncology patients die of the effects of malnutrition rather than of the malignancy itself [1].

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Data on the prevalence of malnutrition in patients with cancer vary widely, ranging between 15% and 80%, depending on the evaluation criteria, the type, site and extent of the tumor, and the anticancer treatment [2].

Resection of the tumor is the main, and potentially curative, step in the management of cancer. Malnutrition can influence the clinical decision making of resecting the tumor negatively. In the case of surgery, malnutrition can increase the incidence of postoperative complications, including delayed wound healing and dehiscence of anastomosis, and overall morbidity and mortality [3].

First-line strategies to counteract malnutrition should include routine screening and identification of patients at nutritional risk, with the use of a simple and standardized screening tool. International nutrition organizations and accredited health care organizations agree that routine nutritional screening should be a standard procedure for every patient admitted to hospital [4]. In the absence of formal screening procedures, more than half of the patients at risk for malnutrition appear to be not unidentified and subsequently not referred for treatment [4].

There is neither a universally accepted definition of malnutrition, nor a "gold standard" screening tool for detection of patients at risk of malnutrition. Over 70 nutrition screening tools have been described in different populations [5], which present differences in validity, reliability, ease of use and acceptability [4].

Nutritional screening is the first step in the design of a nutritional plan during admission. In some countries, namely the United Kingdom (UK), the United States of America (US), the Netherlands and some parts of Denmark, nutrition screening on patient admission is mandatory, with hospital accreditation dependent on this being carried out [4].

In a country such as Greece in the period of crisis, with severe socio-economic hardship, deterioration in the nutritional status of large sections of the population could be expected, making the need for detection of malnutrition in patients admitted to hospital crucial.

This study was performed in one of the largest hospitals in Athens, the capital of Greece, to investigate the prevalence of malnutrition in oncology patients and the relationship between objective variables (anthropometric and laboratory measurements) and subjective scoring systems in the assessment of nutritional status.

To our knowledge, this is the first comprehensive nutritional assessment study conducted in oncology patients in a Greek hospital.

Subjects and Methods

Subjects

The study included 88 adult patients with cancer, recruited during a period of 11 months at the Sismanoglio General Hospital in Athens. The patients had been admitted to one of three clinics, Surgery, Thoracic Surgery and Hematology. The exclusion criteria were age < 18 years, burns, peritoneal or hemodialysis rehydration perfusion and endocrine diseases. Patients undergoing palliative surgery or palliative anticancer treatment were also excluded from the study.

Each participant was informed of the aims of the study, following which written consent was provided by either the patient or a relative. Out of 91 patients invited to participate, 3 declined, for personal reasons.

The study protocol was approved by the Medical Research Ethics Committee of the Sismanoglio General Hospital (Ref. No 5202/7-3-12).

Anthropometric measurements

Body weight was measured to the nearest 0.01 kg with the patient standing without shoes and wearing light clothes. Body height was measured to the nearest 0.5 cm with a stadiometer in patients who could stand, and recumbent height was measured in patients who were unable to stand. Body mass index (BMI) was derived as weight (kg), divided by height (m) squared (kg/m^2). Triceps skinfold thickness (TSF) as an indicator of body fat stores, was measured to the nearest 0.01 mm, with a precision caliper (Harpenden Skinfold Caliper, HSK-BI), on the posterior upper arm midway between the acromion and olecranon processes. Midarm circumference (MAC) was measured to the nearest 0.01 cm by a measuring tape placed around the patient's upper arm, in the same location as the TSF measurement. MAC and TSF were used to calculate midarm muscle circumference (MAMC) according to the following formula: MAMC (cm) = MAC (cm) – TSF (mm) x 0.3142. MAMC estimates muscle mass or lean tissue stores.

All anthropometric measurements were made at least three times, by the same investigator, and reported values are the means of the repeated measurements.

Laboratory data

The laboratory data was derived from the patients' routine blood tests, recorded in their files. For the purposes of the study, values were retrieved of serum albumin, total protein, ferritin, vitamin B12 and folic acid, and also hematological measurements, hematocrit (Ht), hemoglobin (Hb), white blood count (WBC), platelet count (PLT), prothrombin time (pT), and partial prothromboplastin time aPTT). All the samples were analysed in the core laboratory of the Sismanoglio Hospital, using standard laboratory methods.

Nutritional screening tools

The nutritional status of the study participants was evaluated using three nutrition screening tools: Subjective Global Assessment (SGA), recommended by the American Society of Parenteral and Enteral Nutrition (ASPEN), Nutrition Risk Screening 2002 (NRS 2002), recommended by the European Society of Clinical Nutrition and Metabolism (ESPEN) and the Malnutrition Screening Tool (MST), which has been validated for inpatients and oncology outpatients receiving radiotherapy.

NRS-2002

NRS-2002 [6], consists of a nutrition score (0-3 points) and a severity of disease score (0-3 points), with age adjustment for patients aged >70 years (+1 point). The total score (the sum) can range from 0 to 7. Patients are classified as no risk = 0, low risk = 1-2, medium risk = 3-4 and high risk ≥5. The scale is based on clinical and subjective assessment (weight loss, food intake, BMI) and is very easy to use and quick to complete (2-3 min).

SGA

SGA [7] is an assessment tool, rather than a screening tool. It uses a questionnaire comprising items covering medical history and clinical findings (weight loss, changes in dietary intake, gastrointestinal symptoms, symptoms that can influence nutritional intake, functional capacity, nutrition-related physical examination and the clinician's overall judgment of the patient's nutritional status). Normally nourished patients are classified as "grade A", patients with moderate malnutrition as "grade B" and severely malnourished as "grade C". SGA is efficient, cost-effective and easy to learn, and shows a high degree of inter-rater agreement.

MST

MST [8] is a short, easy screening tool that combines questions regarding appetite and recent unintentional weight loss. A score of ≥2 means that the patient is at risk for malnutrition and warrants further assessment.

Statistical analysis

The data was analyzed with the use of SPSS software (version 13.0; SPSS Inc, Chicago, IL). Differences between the independent groups were assessed by Student's *t* test and one-way analysis of variance. Data are presented as mean ± standard deviation (SD) and the χ^2 test was used to compare the differences in the prevalence of nutritional risk. Statistical significance was set at P<0.05 level (two-tailed).

To compare the tools, the nutritional assessment results were reorganized into two categories: A, in good nutritional status: (NRS-2002, no risk = 0 and low risk = 1-2; SGA, normally nourished patients "grade A", MST a score of 0-1), and B, at nutritional risk: (NRS-2002, medium risk = 3-4 and high risk ≥5; SGA, patients with moderate malnutrition "grade B" and severely malnourished patients "grade C"; MST a score of ≥2). SGA was considered the gold standard for evaluation of sensitivity, specificity and predictive values for tools.

Results

Between April 2012 and February 2013, 88 patients with cancer (34 women, 54 men), were consecutively enrolled in the study. Of these, 52 were in the Surgery clinic, 20 in the Thoracic Surgery clinic and 16 in the Hematology clinic. The mean age of the patients was 69.12±13.34 years. The primary cancer diagnosis in the study population is shown in Table 1.

The nutritional status and laboratory parameters of the patients were assessed within 48 hours of admission. All the patients were evaluated with all three nutrition screening tools. For comparison purposes, the results were reorganized into two categories as described on the methods section, A good nutritional status, and B at nutritional risk, i.e., with some degree of malnutrition. The prevalence of malnutrition at admission was 45.5% when determined with either SGA (grade B + grade C) and NRS-2002 (a score of ≥3). The frequency of any degree of malnutrition was 35.3% according to the MST (score of ≥2).

The sensitivity of the tool was 95.8% for NRS-2002 and 84.2% for MST, and the specificity was 95.0% and 100% for NRS-2002 and MST respectively.

The three screening tools showed statistically significant differences in the degree of nutritional risk when patients were stratified by age (>70years and <70years). Patients aged >70 years had a greater nutritional risk (NRS 2002: 56.25%, SGA: 54.16% and MST: 39.58%) than patients aged <70 years (NRS 2002: 32.5%, SGA: 35% and MST: 30%).

Significant differences in nutritional status were demonstrated between the sexes. According to SGA, the males showed a higher prevalence of malnutrition (51.85%) than the females (35.29%).

Weight loss in the previous 6 months was reported by 67% of patients in our study, and 20% of patients experienced decrease in appetite.

Malnutrition scores on the screening tools were demonstrated to be correlated significantly with the weight loss (P<0.0001) and percentage weight loss (P<0.0001) (Table 2).

The anthropometric data were lower in the malnourished groups, based on all three screening tools (Table 3). All three anthropometric indices were lower in patients who were malnourished according to SGA (TSF P<0.001, MAC P<0.0001 and MAMC P<0.001). Regarding BMI, the results were more complicated (Table 4). In this study the patients were categorized into 4 different groups according BMI values (A: BMI <18.5 kg/m², B: BMI 18.6-24.9 kg/m², C: BMI 25-29.99 kg/m², D: BMI >30 kg/m²). There was significant correlation between subjective assessment of malnutrition and BMI, but this varied between tools, showing the limitations of using BMI as the sole measurement of nutritional status.

Table 1. *Primary site of cancer in the study population assessed for malnutrition.*

Site of cancer	n (%)
Stomach	11 (12.5%)
Colon-rectum	36 (40.9%)
Small bowel	3 (3.4%)
Pancreas	1 (1.1%)
Lung	20 (22.7%)
Blood malignancies	16 (18.2%)
Bladder	1 (1.1%)

Table 2. *Weight differences according to nutritional status as assessed by screening tools in patients with cancer (n=88) (mean ± SD).*

	SGA			NRS 2002			MST		
	Well-nourished (n=48)	Mal-nourished (n=40)	*P* value	Well-nourished (n=48)	Mal-nourished (n=40)	*P* value	Well-nourished (n=57)	Mal-nourished (n=31)	*P* value
Weight (kg)	79.71±17.45	67.15±12.30	*P*<0.0001	78.71±17.33	68.35±13.58	*P*<0.003	78.01±17.14	66.63±12.40	*P*<0.002
Weight loss (kg)	1.16±1.56	9.72±5.88	*P*<0.0001	1.25±1.60	9.62±6.02	*P*<0.0001	1.73±2.05	11.16±5.89	*P*<0.0001
Weight loss (%) kg	1.39±1.84	12.46±7.09	*P*<0.0001	1.52±1.96	12.31±7.29	*P*<0.0001	2.17±2.52	14.25±7.07	*P*<0.0001

SGA: Subjective Global Assessment; NRS 2002: Nutritional Risk Screening 2002; MST: Malnutrition Screening Tool

Table 3. *Anthropometric data of patients with cancer (n=88) according to nutritional status assessed by nutrition screening tools (mean ±SD).*

	SGA			NRS 2002			MST		
	Well-nourished (n=48)	Mal-nourished (n=40)	*P* value	Well-nourished (n=48)	Mal-nourished (n=40)	*P* value	Well-nourished (n=57)	Mal-nourished (n=31)	*P* value
TSF (mm)	16.87±4.91	13.44±4.58	*P*<0.001	16.71±4.86	13.63±4.79	*P*<0.004	16.48±5.14	13.17±4.12	*P*<0.003
MAC (cm)	29.97±4.15	26.77±3.88	*P*<0.0001	29.76±4.09	27.03±4.14	*P*<0.003	29.54±4.10	26.63±4.11	*P*<0.002
MAMC (cm)	24.66±3.04	22.55±2.86	*P*<0.001	24.50±3.01	22.74±3.02	*P*<0.008	24.36±2.93	22.50±3.15	*P*<0.007

SGA: Subjective Global Assessment; NRS 2002: Nutritional Risk Screening 2002; MST: Malnutrition Screening Tool, TSF: triceps skinfold thickness; MAC: midarm circumference; MAMC: midarm muscle circumference

Table 4. *Evaluation of nutritional risk according to the body mass index (BMI) of patients with cancer (n=88).*

	SGA		NRS 2002		MST	
BMI (kg/m^2)	Well-nourished	Malnourished	Well-nourished	Malnourished	Well-nourished	Malnourished
<18.5	0	6	0	6	0	6
18.5-24.9	13	16	13	16	17	12
25-29.99	20	15	21	14	24	11
>30	15	3	14	4	16	2
	48	40	48	40	57	31
	P<0.002		*P*<0.005		*P*<0.001	

SGA: Subjective Global Assessment; NRS 2002: Nutritional Risk Screening 2002; MST: Malnutrition Screening Tool

The laboratory data also showed differences, but not always significant, between the malnourished and well-nourished groups (Table 5). Serum albumin (P<0.0001) and total protein (P<0.005) were significantly lower in malnourished patients according to SGA, but not ferritin (P=0.875), folic acid (P=0.066), B12 (P=0.265), WBC (P=0.474), Ht (P<0.041), Hb (P=0.06), PLT (P=0.670), PT (P=0.696) or aPTT (P=0.363).

Malnutrition according to tumor site was also calculated (Table 6). The numbers were small, but stomach cancer appeared to be associated with a greater degree of malnutrition.

Discussion

Malnutrition is common among patients with cancer, and early identification and assessment is crucial [9], but the simple correction of their nutritional status appears to be overlooked or not considered as a medical priority [10].

Many nutrition screening tools have been validated for use by clinicians. In our study, we evaluated three tools, SGA, NRS 2002 and MST, for their appropriateness for use with cancer patients. SGA and NRS 2002 have been validated with mixed populations and, to a certain extent, with patients with cancer. NRS 2002 is currently recommended by ESPEN for nutritional screening in European hospitals [6],

Table 5 *Laboratory data in patients with cancer according to nutritional status as assessed by nutrition screening tools (n=88) (mean ± SD).*

	SGA			NRS 2002			MST		
	Well-nourished (n=48)	Mal-nourished (n=40)	*P* value	Well-nourished (n=48)	Mal-nourished (n=40)	*P* value	Well-nourished (n=57)	Mal-nourished (n=31)	*P* value
Albumin (g/dl)	4.13±0.58	3.58±0.69	*P*<0.0001	4.13±0.59	3.59±0.68	*P*<0.0001	4.11±0.57	3.48±0.70	*P*<0.0001
Total protein (g/dl)	6.90±0.88	6.32±0.97	*P*<0.005	6.89±0.901	6.33±0.96	*P*<0.006	6.87±0.84	6.20±1.03	*P*<0.001
Ferritin	221.04±267.06	203.83±434.19	*P*=0.875	202.86±257.45	226.73±433.60	*P*=0.826	201.07±255.09	238.85±486.59	*P*=0.742
Folic acid	10.33±10.51	6.25±3.55	*P*=0.066	10.83±10.75	6.01±3.47	*P*<0.040	9.66±9.89	6.35±3.52	*P*=0.231
B12	876.82±1856.25	392.84±160.40	*P*=0.265	935.26±1916.13	366.57±173.38	*P*=0.144	800.18±1715.80	400.64±168.90	*P*=0.392
WBC (K/μl)	7.88±3.37	8.43±3.78	*P*=0.474	7.88±3.15	8.44±4.01	*P*=0.465	7.95±3.33	8.48±3.96	*P*=0.509
Ht (%)	37.58±6.96	34.43±7.24	*P*<0.041	37.92±6.85	34.02±7.17	*P*<0.011	37.26±6.81	34.10±7.62	*P*<0.050
Hb (g/dl)	12.00±2.62	10.94±2.59	*P*=0.060	12.07±2.62	10.85±2.55	*P*<0.031	11.86±2.58	10.90±2.70	*P*=0.106
PLT (K/μl)	247.39±112.28	259.07±143.95	*P*=0.670	259.04±103.24	245.10±151.78	*P*=0.693	249.33±112.54	258.90±151.94	*P*=0.738
PT (sec)	12.42±3.45	12.66±1.75	*P*=0.696	12.38±3.45	12.72±1.76	*P*=0.574	12.39±3.18	12.78±1.94	*P*=0.538
aPTT (sec)	31.53±4.67	32.69±7.09	*P*=0.363	31.21±4.57	33.07±7.08	*P*=0.141	31.32±4.61	33.41±7.60	*P*=0.111

SGA: Subjective Global Assessment; NRS 2002: Nutritional Risk Screening 2002; MST: Malnutrition Screening Tool; WBC: white blood cell count; Ht: hematocrit; Hb: hemoglobin; PLT: platelet count; PT; prothrombin time; aPTT: partial prothromboplastin time

Table 6 *Prevalence of malnutrition in patients with cancer as measured by malnutrition assessment tools according to the tumor site (n=88)*

	SGA			NRS 2002			MST		
	Well-nourished	Malnourished	Total	Well-nourished	Malnourished	Total	Well-nourished	Malnourished	Total
Stomach	3 (27.28%)	8 (72.72%)	11	4 (36.37%)	7 (63.63%)	11	5 (45.46%)	6 (54.54%)	11
Colon-rectum	19 (52.78%)	17 (47.22%)	36	20 (55.56%)	16 (44.44%)	36	24 (66.67%)	12 (33.33%)	36
Blood malignancies	9 (56.25%)	7 (43.75%)	16	7 (43.75%)	9 (56.25%)	16	11 (68.75%)	5 (31.25%)	16
Lung	14 (70%)	6 (30%)	20	14 (70%)	6 (30%)	20	14 (70%)	6 (30%)	20
Small bowel	1	2	3	1	2	3	1	2	3
Bladder	0	1	1	0	1	1	0	1	1
Pancreas	1	0	1	1	0	1	1	0	1
Total	47	41	88	47	41	88	56	32	88

SGA: Subjective Global Assessment; NRS 2002: Nutritional Risk Screening 2002; MST: Malnutrition Screening Tool

while MST has been validated for oncology patients [8], together with another screening tool, the Patient-Generated Subjective Global Assessment (PG-SGA) [11,12]. We excluded the use of PG-SGA for our study, because it is more time-consuming, requires more examiner training than the other tools [12,13] and relies on patient literacy.

The prevalence of malnutrition in the hospital studied varied, depending on the tool, between45.5% using SGA

and NRS 2002 and 35.3% using MST. This lack of total agreement between the tools could be attributed to the different parameters used by each tool. In addition, our sample included all types of cancer, and screening with population-specific tools may be indicated.

Our results are consistent with the high prevalence of malnutrition found in other studies in hospitalized oncology patients [10] and cancer outpatients [14], and revealed better agreement between the tools [10].

The assessment tools NRS-2002 and SGA include more parameters (objective and clinical) than the MST screening tool. It is considered that a new tool combining screening and assessment techniques should be researched and developed [15].

A good nutritional screening tool should be highly sensitive and specific. In this study, MST showed higher specificity (100%) than NRS 2002 (95%); that is, non-malnourished patients were classified as not being at nutritional risk. NRS 2002 showed high sensitivity (95.8%) meaning that patients at nutritional risk were correctly identified. NRS 2002 and MST had good positive and negative predictive values. A principal limitation of our study was that we compared the nutritional variables with the SGA, but this is a tool which is widely recommended and has been chosen as the reference method in other studies [16,17,18].

All the screening tools identified elderly patients to be at higher nutritional risk at rates varying between 39.58% and 56.25% depending on the tool. NRS 2002, which has an age adjustment for patients aged over 70 years detected a higher percentage (56.25%) of elderly patients at nutritional risk than SGA (54.16%) and MST (39.58%). Malnutrition is a common phenomenon in elderly people, affected by physiological, social and economic factors [19]. In another Greek study, the risk of malnutrition was found in 66.9% of elderly patients on admission [19].

A gender difference was also found, with men being at greater nutritional risk (51.85%) than women (35.29%), and losing more muscle mass. These rates are similar to those in the international literature [20].

Weight loss is widely used as an accurate indicator of malnutrition among oncology patients, either alone or in combination with other means of assessment [21]. In this study, weight change, specifically the percentage of weight loss over the previous 6 months, was reported in 67 % of patients, and was more common than anorexia. This figure approximates the rate (60.4%) documented in large epidemiological observational study of non-selected adults with cancer [22]. Weight loss, anorexia, inflammation, insulin resistance and increased muscle protein breakdown are known to be associated with cancer cachexia [23].

Our results suggest that BMI alone fails to detect malnutrition among cancer patients, but the screening tools can detect malnutrition before the BMI drops below 20kg/m^2. Previous studies on cancer patient groups also highlighted the limitations of using BMI as the sole measure of nutritional status [22,24] while there is one report of obesity (BMI>30kg/m^2) as a possible risk factor for malnutrition in a large non-selected population of patients suffering from cancer [22].

All the anthropometric measurements showed a difference between the malnourished and well-nourished groups. The mean values of MAC (P<0.0001), TSF (P<0.001) and MAMC (P<0.001) in the oncology patients differed statistically from the norm [25]. These results can be explained by the loss of skeletal muscle and adipose tissue mass in cancer cachexia [23].

The low serum albumin is a powerful predictor of surgery-related morbidity and thus is of great value in the clinical setting, continuing to be an important part of the general evaluation of patients with cancer [17]. It has been reported, however, that low serum protein levels do not always indicate malnutrition and that malnutrition does not always accompany low serum protein levels [25]. For these reasons, hypoalbuminemia is considered to be a predictor of risk in the broad sense, rather than a parameter that indicates malnutrition [25]. In our study, the serum albumin (P<0.0001) and total proteins (P<0.005) were reduced significantly in the malnourished patients, as was the ht. This is in agreement with other studies which showed that protein deficiency can directly affect erythropoiesis, and therefore ht usually decreases in conditions of malnutrition (26). The lymphocyte count, platelets, ferritin, B12, folic acid, pT and aPTT showed no significant decrease in the malnourished patients, in accordance with previous studies [26].

The highest risk of malnutrition, according to SGA, was associated with stomach tumors (72.72%) followed by colon-rectum cancer (47.22%), blood malignancies (43.75%) and lung cancer (30%). Other investigators also found the prevalence of malnutrition at GI cancer patients to be notably high (70.6%) [27].

Assessment with NRS 2002 placed the patients with hematologic malignancies the second highest position of malnutrition, with a percentage of 56.25%, followed by those with colon-rectum cancer 44.44%. This differentiation could be expected, as an additional unit is added for hematologic malignancies to the calculation of the final score of this tool, which makes NRS a more sensitive index for these patients. The patients with lung cancer were identified as being in a better nutritional state, with a nutritional risk at 30% according to all three nutritional tools, but these patients did not have metastatic lung cancer. In a recent Greek study [28], malnutrition was detected in 76.5% of patients with metastatic lung cancer, using MNA.

In conclusion, this study shows a high prevalence of

nutritional risk in patients with cancer in Greece, identified with all the nutrition screening tools applied. One disadvantage in the present study was the fact that it was a single-center study, and the results are therefore not representative of the total population of patients with cancer, although they can still be considered important. What became clear from conducting this study was the lack of awareness and the absence of nutritional interventions to curtail or prevent malnutrition in oncology patients. By the time the patients seek hospitalization, malnutrition from cancer has already occurred. Thus, the nutritional status of the patient on admission needs to be reevaluated. One main reason for this, especially in Greece, might be the low level of knowledge and awareness of nutritional problems among caregivers (GrESPEN). A nutritional support team and efforts to raise the awareness of caregivers are needed in every hospital in order to overcome, in time, the malnutrition of patients.

Nutrition screening tools are currently not being used in routine practice, while blood tests are not always reliable and anthropometric tests are not always feasible.

It is apparent that in order to ensure more reliable conclusions concerning the nutritional status of oncology patients in Greece, a multi-center study needs to be conducted, including hospitals all over the country, carried out by a team of well trained healthcare workers and including a substantial number of patients.

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