





Original/Valoración nutricional

Cutoff point of the phase angle in pre-radiotherapy cancer patients

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Abstract

Introduction: malnutrition is a common complication for cancer patients. The phase angle (PA), direct measurement of bioelectrical impedance analysis (BIA), has been considered a predictor of body cell mass and prognostic indicator. Cutoff points for phase angle (PA) associated with nutritional risk in cancer patients have not been determined yet.

Objectives: assess the possibility of determining the cutoff point for PA to identify nutritional risk in pre-radiotherapy cancer patients.

Methods: sample group: Patients from both genders diagnosed with cancer and sent for ambulatory radiotherapy. Variables studied: body mass index (BMI), percentage of weight loss (% WL), mid-arm circumference (MAC), triceps skinfold thickness (TST), mid-arm muscle circumference (MAMC), mid-arm muscle area (MAMA), score and categorical assessment obtained using the Patient-Generated Subjective Global Assessment (PG-SGA) form, PA and standardized phase angle (SPA). Kappa coefficient was used to test the degree of agreement between the diagnoses of nutritional risk obtained from several different methods of nutritional assessment. Cutoff points for the PA through anthropometric indicators and PG-SGA were determined by using Receiver Operating Characteristic (ROC) curves, and patient survival was analyzed with the Cox regression

Results: the cutoff points with the greatest discriminatory power were those obtained from BMI (5.2) and the categorical assessment of PG-SGA (5.4). The diagnosis obtained using these cutoff points showed a significant association with risk of death for the patients in the sample group.

Conclusion: we recommend using the cutoff point 5.2 for the PA as a criterion for identifying nutritional risk in pre-radiotherapy cancer patients.

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Key words: Bioelectrical impedance. Cancer. Nutritional assessment. Anthropometry.

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EL PUNTO DE CORTE DE ÁNGULO DE FASE EN PACIENTES CON CÁNCER EN LA PRE-RADIOTERAPIA

Resumen

Introducción: la desnutrición es una complicación frecuente en los pacientes con cáncer. El ángulo de fase (AF), medición directa del análisis de impedancia bioeléctrica (AIB), puede ser considerado un factor de predicción de la masa celular corporal e indicador de pronóstico. Los puntos de corte para el ángulo de fase (PA) que se asocian con el riesgo nutricional en pacientes con cáncer aún no han sido determinados.

Objetivos: evaluar la posibilidad de determinar el punto de corte para el AF para identificar riesgo nutricional en pacientes con cáncer antes de la radioterapia.

Métodos: grupo muestreado: pacientes de ambos sexos con diagnóstico de cáncer y enviados para radioterapia ambulatoria. Variables estudiadas: índice de masa corpórea (IMC), porcentaje de pérdida de peso (% PP), circunferencia del brazo (CB), pliegue cutáneo del tríceps (PCT), circunferencia muscular del brazo (CMB), área muscular del brazo (AMB), puntuación y evaluación categóricas obtenidas utilizando la Valoración Global Subjetiva Generada por el Paciente (VGS-GP), AF y ángulo de fase estandarizado (AFS). El coeficiente Kappa se utilizó para probar el grado de concordancia entre los diagnósticos de riesgo nutricional obtenidos de diferentes métodos de evaluación nutricional. Los puntos de corte del AF a través de indicadores antropométricos y VGS-GP se determinaron utilizando la curva ROC (Receiver Operating Characteristic), y la sobrevivencia de los pacientes se analizó con el método de regresión de Cox.

Resultados: los puntos de corte con mayor poder discriminatorio fueron los obtenidos de IMC (5,2) y la evaluación categórica del VGS-GP (5,4). El diagnóstico obtenido mediante estos puntos de corte mostró una asociación significativa con el riesgo de muerte de los pacientes incluidos en este trabajo.

Conclusión: se recomienda utilizar el punto de corte 5.2 para el AF como criterio para la identificación de riesgo nutricional en pacientes con cáncer antes de la radioterapia.

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Palabras clave: Impedancia bioeléctrica. Cáncer. Evaluación nutricional. Antropometría.

Abbreviations:

AUC: Area under the curve.

BIA: Bioelectrical impedance analysis.

BMI: Body mass index. CI: Confidence intervals. MAC: Mid-arm circumference. MAMA: Mid-arm muscle area.

MAMC: Mid-arm muscle circumference.

PA: Phase angle.

PG-SGA: Patient-generated subjective global assessment.

R: Resistance.

ROC: Receiver operating characteristic.

SD: Standard deviations . SPA: Standardized phase angle. TST: Triceps skinfold thickness. WHO: World Health Organization.

WL: Weight loss.Xc: Reactance.Z: Impedance.

Introduction

Malnutrition is a common complication for cancer patients, and its incidence varies between 40 and 80%, depending on tumor type, localization, stage and method of treatment¹. It's consequences include increase in risk of further complications, hindered response and tolerance to treatment, greater risk of infection, decreasing quality of life and life expectancy, increasing time in hospital, morbidity and mortality^{1,2,3,4,5}.

Several factors are involved in the development of malnutrition in cancer patients, related to the presence of the tumor, like metabolic changes and increased caloric demand for tumor growth and the side effects of treatment, that can leads to reduced appetite and mechanical difficulties to chew and swallow food³. Therefore nutritional assessment needs to be performed at the beginning of and throughout all the treatment^{3,4,6}, in order to identify patients who are at nutritional risk or malnourished, so as to initiate appropriate nutritional therapy^{1,7}.

Historically nutritional assessments have been carried out using anthropometric and biochemical parameters, and clinical and subjective evaluation^{8,9,10}. However, none of these methods is considered a "gold standard,"^{5,7,11} as they all have their limitations. These methods can be influenced by factors unrelated to nutritional status^{7,8,10,12}.

Malnutrition can be detected early through changes in the cell membrane and body fluids that are analyzed by using Bioelectrical Impedance Analysis (BIA)¹⁰. BIA is a simple, noninvasive and reproducible technique that has been validated for the assessment of body composition and nutritional status for various different types of patients, including patients with cancer¹³.

Such analysis is based on the measurement of the resistance (R) and reactance (Xc) to the passage of

an electrical current through human tissues⁷. The R, which reflects the opposition to an electrical current running through the body, is inversely proportional to the quantity of fluids. In the human body, lean mass is highly conductive, for containing a large quantity of water and electrolytes, thus representing a medium of low electrical resistance. Fat and bone, however, contain little water and electrolytes which means that they are bad conductors of electricity so they have high resistance. Reactance, though, is the opposition to the flow of the electric current as caused by the capacitance of the cell membranes, and variations may occur as influenced by its integrity, function and composition¹⁴.

Phase angle (PA) is a parameter obtained from the relation between the direct measurement of R and Xc, being calculated by the equation PA=arctan Xc/R x 180°/3.14. The advantage of using PA is that it is applicable even on patients with alterations in fluids or whose body weight is immeasurable, making BIA even more applicable in clinical practice. It has been interpreted as an indicator of cell membrane integrity, reflecting the volume of cell mass and its functional state. Its values can vary between 0 and 90 degrees, with a healthy individual presenting PA values of approximately 4 to 10 degrees¹⁴. Lower phase angles suggest cell death or decreased cell integrity, while higher phase angles suggest large quantities of intact cell membranes⁸.

Cutoff points for PA associated to nutritional risk have not been determined yet¹⁵. While the relation between PA and other nutritional status markers is still under discussion, there is a need for further study¹⁶.

Considering how important it is to identify safe ways of assessing cell health and nutritional status in cancer patients undergoing treatment, the main aim of this study is to assess the possibility of determining a cutoff point for PA, with which to identify nutritional status in cancer patients, based on methods of nutritional assessment commonly used in clinical practice.

Methods

Sampling

The study group consists of 93 male and female patients above 18 years old who attended public health care system hospitals and Pedro Ernesto University Hospital and sent for outpatient radiotherapy at the high complexity oncology unit of this hospital. All of them had been given histopathological diagnoses, staging and treatment requests. The data collected for this study are part of nutritional risk diagnosis routine at the oncological nutritional outpatient clinic of this hospital and it was collected between May and November of 2009.

The protocol for this study was approved by the Pedro Ernesto University Hospital Research Ethics Committee (No. 2553), and all the patients signed a consent form as an agreement to participate.

Collected data

Data was collected during the first nutritional consultation prior to the first radiotherapy session, and the data was recorded on an electronic form with general information on each patient, their medical records, anthropometric nutritional assessment, Patient-Generated Subjective Global Assessment (PG-SGA), and BIA assessment.

Criteria for inclusion/exclusion

The patients were required to have been scheduled for radiotherapy that could be either exclusive, adjuvant, neoadjuvant, combined or not with chemotherapy in order to take part in the study. Patients scheduled for palliative radiation therapy were excluded.

Variables obtained through anthropometric assessment

Body mass index (BMI) – Cutoff points established by the World Health Organization (WHO) in 1998 were used to classify BMI 17 . Patients with BMI \leq 18.5 kg/m 2 were considered at nutritional risk for statistical analysis.

Percentage of weight loss (%WL) – was interpreted according to Blackburn, with patients classified as being at nutritional risk if their weight loss was greater than 10% over a 6-month period¹⁸.

Mid-arm circumference (MAC) and triceps skinfold thickness (TST) – were measured as described by Heymsfield and collaborators¹⁹.

Mid-arm muscle circumference (MAMC) – was measured using the formula recommended by Frisancho²⁰.

Mid-arm muscle area (MAMA) – was obtained using the formula suggested by Grant and collaborators²¹.

It was used the 50 percentiles for sex and age put forward by Frisancho in 1990²² and NHANES III²³ to calculate percent of skinfold adequacy and circumferences and classified them according to Blackburn and Thornton²⁴, considering patients with adequacy under 90% at nutritional risk.

Variables obtained through BIA

The BIA was performed using a Biodynamics tetra polar model 450 device at the same time as anthropometric and PG-SGA measurements were taken during the morning, on fasting and according to the criteria defined by Heyward & Storlaczyl²⁵, thus obtaining the R, Xc and PA values.

PA was standardized by using reference values for sex and age according to the following equation: Standardized Phase Angle (SPA)=[(observed PA – average

PA for sex and age) / Standard deviation of PA for sex and age].

Patients with values below -1.65 standard deviations (SD) were considered at nutritional risk, such value being considered as the minimum acceptable limit for a healthy population 10.

Variables obtained through the PG-SGA

The PG-SGA data was collected through a questionnaire that patients classified as B or C and those with scores greater or equal to 4 in the numeric score were considered at nutritional risk²⁶.

Statistical analysis

Kappa coefficient was used to test the degree of agreement between methods of nutritional assessment in the nutritional risk diagnoses. The following criteria was used to interpret the kappa values: k < 0.2 – poor agreement; $0.21 \le k \le 0.40$ – fair agreement; $0.41 \le k \le 0.60$ – moderate agreement; $0.61 \le k \le 0.80$ – good agreement; k > 0.80 – very good agreement²⁷.

Cutoff points for PA were determined by using anthropometric indicators and the PG-SGA as golden standards with Receiver Operating Characteristic (ROC) curves.

The area under the curve (AUC) and the 95% confidence intervals (CI) was determined. The greater the AUC, the greater the discriminatory power of the PA; a 95% CI should not include the value 0.50.

Assessment of patient survival according to the phase angle cutoff points identified was performed using Cox regression analysis.

For statistical purposes, significance level was set at 5% (p<0.05).

Results

This study investigated 93 patients with cancer, 72% were male (n=67) and 28% were female (n=26).

Considering the sample group as a whole, 53.8% (n=50) were recommended for adjuvant radiation therapy, 39.8% (n=37) for exclusive radiation therapy, and 6.4% (n=6) for neoadjuvant radiation therapy.

Prostate cancer was the most common cancer among the males, with 52.2% (n=35), followed by orophary-nx (20,9 %, n=14), rectal (11,9%, n=8), hematological (6%, n=4), bladder (1,5%, n=1), esophagus (1,5%, n=1), lung (1,5%, n=1), testicular (1,5%, n=1), bone (1,5%, n=1), neurological (1,5%, n=1). For famales, the breast cancer was the most common type of cancer, with 38.5% (n=10), followed by gynecological (23,1%, n=6), rectal (11,5%, n=3), oropharynx (7,7%, n=2), hematological (7,7%, n=2), urethra 1 (3,8%, n=1), lung (3,8%, n=1), neurological (3,8%, n=1).

Table I shows the characteristics of the study group. On average they were 62 years old, they were classified as overweight according to BMI, and at nutritional risk according to PG-SGA score.

According to the categorical assessment of PG-SGA, 88.2% (n=82) of the patients in the sample group were classified as being well-nourished, and 11.8% (n=11) were moderately malnourished or at risk of malnourishment. No patients were found to be severely malnourished.

Table I					
Characteristics of the study group					

Variable	Median and Standard Deviation
Age (years)	62 ± 12.74
BMI (kg/m²)	25.95 ± 4.11
% WL (%)	0.37 ± 17.58
MAC (cm)	29.83 ± 4.04
TST (mm)	16.85 ± 7.27
MAMC (cm)	24.53 ± 3.29
MAMA (cm ²)	39.77 ± 12.3
PG-SGA score (points)	4 ± 4
PA (°)	5.95 ± 1.00
SPA	-1.04 ± 0.98

BMI=body mass index; %WL=percentage of weight loss; MAC=mid-arm circumference; TST=triceps skinfold thickness; MAMC=mid-arm muscle circumference; MAMA=mid-arm muscle area; PG-SGA=patient generated subjective global assessment; PA=phase angle; SPA=standardized phase angle.

Different percentages of patients at nutritional risk were found according to the different study variables (Table II). Using BMI, only 4.3% (n=4) of the patients were at nutritional risk, while for the other nutritional assessment methods the values varied from 11.8% (n=11) for the PG-SGA categorical to 60.5% (n=49) for the MAMA.

Table III shows the agreement in diagnosing nutritional risk between the study variables according to kappa coefficient. Very good agreement was not found between any of the variables. The only good agreement found was between MAC and TST (k=0.62), and moderate agreement was found between MAC and MAMC (k=0.51), AC and MAMA (k=0.49), MAMC and MAMA (k=0.48) and %WL and PG-SGA categorical (k=0.46). The other agreement coefficients found were either fair or poor.

The PA cutoff points established using the ROC curves from each nutritional assessment method can be found in table IV. All the areas under the curve were above 0.5, though the confidence interval of the ROC curve for MAMC included 0.5. The cutoff points varied from 5.2 (BMI) to 6.1 (MAMA).

Table V shows the risk of death according to Cox Regression for diagnoses generated using the PA cutoff points found in this research. The cutoff points obtained using BMI and the categorical assessment of PG-SGA can be considered independent prognostic factors for the survival of these patients.

Discussion

In this study the nutritional risk was assessed for patients of both genders with cancer prior to radiothe-

Table IINutritional Risk by study variables

	Nutritional Risk					
Variable	Yes		No		n	
	Frequency	%	Frequency	%		
BMI	4	4.3	89	95.7	93	
%WL	16	17.2	77	82.8	93	
MAC	28	30.1	65	69.9	93	
TST	24	26.1	68	73.9	92	
MAMC	42	45.7	50	54.3	92	
MAMA	49	60.5	32	39.5	81	
PG-SGA score	38	40.9	55	59.1	93	
PG-SGA Categorical	11	11.8	82	88.2	93	
SPA	21	22.6	72	77.4	93	

BMI=body mass index; %WL=percentage of weight loss; MAC=mid-arm circumference; TST=triceps skinfold thickness; MAMC=mid-arm muscle circumference; MAMA=mid-arm muscle area; PG-SGA=patient generated subjective global assessment; PA=phase angle; SPA=standardized phase angle.

Table IIIAgreement of nutritional risk diagnosis between study variables according to kappa coefficient (k)

	BMI	%WL	MAC	TST	МАМС	MAMA	PG-SGA score	PG-SGA categorical	SPA
BMI	X	0.26	0.19	0.23	0.07	0.05	0.12	0.36	0.09
%WL	X	X	0.20	0.26	0.12	0.09	0.23	0.46	0.18
MAC	X	X	X	0.62	0.51	0.49	0.30	0.10	0.14
TST	X	X	X	X	0.34	0.25	0.24	0.14	0.14
MAMC	X	X	X	X	X	0.48	0.11	0.04	0.11
MAMA	X	X	X	X	X	X	0.16	0.10	0.09
PG-SGA score	X	X	X	X	X	X	X	0.27	0.25
PG-SGA categorical	X	X	X	X	X	X	X	X	0.26
SPA	X	X	X	X	X	X	X	X	X

k < 0.2 – poor agreement; $0.21 \le k \le 0.40$ – fair agreement; $0.41 \le k \le 0.60$ – moderate agreement; $0.61 \le k \le 0.80$ – good agreement; k > 0.80 – very good agreement.; BMI = body mass index; %WL=percentage of weight loss; MAC=mid-arm circumference; TST=triceps skinfold thickness; MAMC=mid-arm muscle circumference; MAMA=mid-arm muscle area; PG-SGA=patient-generated subjective global assessment; PA=phase angle; SPA=standardized phase angle.

Table IV PA cutoff points and areas under the curve (AUC) according to ROC curve				
	Cutoff point	AUC	CI 95%	
BMI	5.2	0.92	0.73-1.10	
%WL	5.9	0.70	0.55-0.85	
MAC	5.9	0.65	0.52-0.77	
TST	5.7	0.65	0.51-0.78	
MAMC	6.1	0.60	0.48-0.71	
MAMA	6.1	0.68	0.56-0.79	
PG-SGA score	5.9	0.72	0.61-0.83	
PG-SGA categorical	5.4	0.84	0.69-0.99	

BMI=body mass index; %WL=percentage of weight loss; MAC=mid-arm circumference; TST=triceps skinfold thickness; MAMC=mid-arm muscle circumference; MAMA=mid-arm muscle area; PG-SGA=patient-generated subjective global assessment; PA=phase angle; SPA=standardized phase angle.

Table V	
Risk of death through Cox Regression for diagnostics generated using the PA	cutoff points found

Variable	Relative Risk	p-value
BMI PA (1:≤5.2 and 0:>5.2)	2.84	0.015
%WL PA (1:≤5.9 and 0:>5.9)	1.84	0.17
MAC PA $(1: \le 5.9 \text{ and } 0: > 5.9)$	1.84	0.17
TST PA $(1: \le 5.7 \text{ and } 0: > 5.7)$	2.08	0.087
MAMA PA $(1: \le 6.1 \text{ and } 0: > 6.1)$	1.32	0.53
PG-SGA score PA (1:≤5.9 and 0:>5.9)	1.84	0.17
PG-SGA categorical PA (1:≤5.4 and 0:>5.4)	2.85	0.015

BMI PA=Cutoff point for phase angle obtained from body mass index; %WL PA=Cutoff point for phase angle obtained from percentage of weight loss; MAC PA=Cutoff point for phase angle obtained from mid-arm circumference; TST PA=Cutoff point for phase angle obtained from triceps skinfold thickness; MAMA PA=Cutoff point for phase angle obtained from mid-arm muscle area; PG-SGA PA=Cutoff point for phase angle obtained from patient-generated subjective global assessment; 1: nutritional risk, and 0: no nutritional risk.

rapy. In clinical practice, it is important the early identification of patients at greatest risk that allows appropriate nutrition intervention, leading to improvements in nutritional status, quality of life, patient satisfaction and a better recovery¹.

As the sample group was composed of patients undergoing curative treatment is was not verified weight loss among them. Furthermore, 58.2% (n=35) of the men had prostate cancer, and 38.5% (n=10) of the females had breast cancer. Published studies have shown the high prevalence of obesity and overweight with these two types of disease, with obesity considered a risk factor to poor outcomes^{28,29}.

The use of anthropometry, mainly BMI, for assessing nutritional risk in cancer patients has received criticism in recent studies because of the method's limitations. Anthropometric criteria are only useful for better assessing chronic malnutrition, as changes in body composition occur later on in the malnourishment process⁹ and also are time consuming and require well-trained staff³⁰. As found in this study, BMI on its own was shown to be an indicator that underestimates nutritional risk because only 4.3% of the patients were classified as malnourished by these criteria.

Regarding the agreement assessment through the kappa coefficient, it was found that only MAC and TST showed good agreement and MAC and MAMC, MAC and MAMA, MAMC and MAMA and %WL and PG-SGA categorical showed moderate agreement. For the other methods agreements were fair or poor, suggesting that each method may reveal a different aspect of malnutrition. This better agreement, found between skinfold and circumferences was expected, as they are part of a similar type of assessment and each one relies on the other. The moderate agreement between % WL and PG-SGA categorical can be explained by the fact that this subjective assessment takes into consideration the weight loss that the patients undergo, among other factors. Studies with similar methodology also found poor agreement between nutritional assessment parameters, in chronic kidney disease patients³¹, hospitalized patients^{9,32} and surgical patients^{7,11}.

In this study, we cannot affirm whether there would be poor agreement between these methods in patients with more-aggressive and quicker-evolving types of cancer, as most patients were diagnosed with prostate cancer, where the disease progression does not greatly impacted the deterioration of the nutritional status.

It has been suggested that a combination of several methods of nutritional assessment should be used to identify nutritional risk, considering that only one method is not sensitive enough to correctly assess nutritional status and each one complements the others⁴⁵ though in clinical practice that is impossible to do for all patients most of the time, as it requires time, human and financial resources. Capra recommends that nutritional screening be conducted as soon as possible, so that intervention can take place immediately for patients at nutritional risk, for whom undergoing

multiple measurements just for improving diagnostic precision would be a waste of time and money. Furthermore, this author points out that Subjective Global Assessment as a screening method is sensitive and specific enough to identify malnutrition and that its simplicity and precision continue to show superiority over more-complex methods³³.

Although there is not any method of nutritional assessment universally accepted as being ideal for cancer patients, the Brazilian National Cancer Institute José Alencar Gomes da Silva³, the Oncology Nutrition Practice Group of the American Diet Association⁵ as well as a number of studies^{1,2,6} all endorse the PG-SGA as a screening and nutritional assessment tool for these patients. Nevertheless, there are some significant limitations when using the method in clinical practice, as it relies on the patients collaborating by responding to weight loss and dietary intake related questions, and there are existing studies already addressing the difficulty that patients have in remembering their weight from the previous year^{4,26} and specifying what they ate over the last month, as well as limitations relating to a low level of awareness4.

More recently, use of the BIA derived PA in nutritional assessment has awoken interest for being a direct method, not using regression equations, not requiring a constant level of hydration or weight and height measurements. Furthermore, it is noninvasive, quick and objective in determining nutritional risk, while screening tools, though noninvasive as well, require more time and they are partially subjective¹⁰. PA cutoff points associated with nutritional risk have not been determined yet15. Most authors have proposed cutoff points within the study population, mainly using median or lower quartile or cutoff points created in comparing with a healthy control group, and these cutoff points are therefore not necessarily transferable to other populations so they may not be applicable in general medical practice³⁴.

The results from the ROC curve demonstrate that it was possible to identify cutoff points for all the variables except for the MAMC. No single cutoff point was obtained, the values varied from 5.2 (BMI) to 6.1 (MAMA), with the highest area under the curve found for the value 5.2, generated using BMI, and 5.4, generated using the PG-SGA categorical, respectively, thus representing the cutoff points with the greatest discriminatory power. These results suggest that the cutoff point 5.2 is the most appropriate to be used with these patients.

Next, survival by using the Cox regression method was assessed, which separately predicts risk of death using diagnoses based on the cutoff points found, with the aim of identifying prognostic factors.

The only cutoff points found to have a significant association with risk of death were the ones generated using BMI (5.2) and PG-SGA categorical (5.4), which presented similar relative risks (2.84 and 2.85) and an identical p-value (0.0015), meaning they are potential

predictors of death (Table VI). According to the literature, values between 4.5 and 5.6 were suggested as prognostic indicators of survival in patients with breast cancer (5.6), advanced pancreatic cancer (5.01), colorectal cancer (5.57) and non-small cell lung cancer (5.3 and 4.5)^{8,12,13,30,35}.

This study recommends the cutoff point 5.2, obtained using BMI, and 5.4, obtained using the categorical assessment of PG-SGA, as being adequate for assessing nutritional risk in pre-radiotherapy cancer patients.

Conclusion

In this study, we were able to determine PA cutoff points by using the ROC curve for each of the criteria for assessing nutritional risk, except for MAMC. The cutoff points that presented the greatest discriminatory power were the ones obtained by using BMI and the categorical assessment of PG-SGA, with values of 5.2 and 5.4, respectively. Coincidently, the diagnosis resulting from these cutoff points obtained a significant association with risk of death in patients from the sample group. This suggests that the cutoff point of 5.2 is a criterion for identifying nutritional risk in pre-radiation cancer patients.

The limitations of this study were that the assessments done in patients with different tumor types that included cancer of the prostate and breast, which have less impact on nutritional state, and the sample group for more aggressive tumors was smaller, therefore further studies need to be conducted using more homogenous sample groups with more patients in order to confirm the findings presented here.

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