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The Inflammatory-Nutritional Index; assessing nutritional status and prognosis in gastrointestinal and lung cancer patients

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Abstract

Objective: **To evaluate the prognostic capacity of the Inflammatory-Nutritional Index (INI) in gastrointestinal and lung cancer patients.**

Methods: **Longitudinal study, including patients from a chemotherapy service in Brazil, between July 2008 and May 2010. INI (Albumin/CRP) and nutritional status (by Subjective Global Assessment - SGA) were evaluated. Risk INI was defined as lower than 0.35. The mean follow-up of survival was 1.6 year. Statistical analyses were performed using Stata 11.1™.**

Results: **74 patients participated in the study, mean age 63.4, most of them male (58%) and presenting gastrointestinal cancer (71%). Malnutrition was identified in 87% of the patients (22% severely malnourished). The mean INI was 2.67 and 54% of the patients had INI levels considered as risk. During the follow-up there were 49 deaths (66%). The median survival time for INI risk patients was significantly shorter than for normal INI ones (p = 0,002). It took 0.78 year for the INI risk subsample to decline 50%, while it took 2.78 year for the normal INI subsample. INI risk and severe malnutrition were independent predictors for poor survival.**

Conclusion: **The INI showed prognostic capacity in this sample and may be a useful tool, based on routinely available blood tests, to assess cancer patients.**

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ÍNDICE INFLAMATORIO-NUTRICIONAL; EVALUACIÓN DEL ESTADO NUTRICIONAL Y PRONÓSTICO EN PACIENTES CON CÁNCER DE TRACTO GASTROINTESTINAL Y DE PULMÓN

Resumen

Objetivo: **Evaluar la capacidad pronostica del Índice Inflamatorio-Nutricional (INI) en pacientes con cáncer del tracto gastrointestinal y pulmón.**

Métodos: **Estudio longitudinal, con pacientes de un servicio de quimioterapia en Brasil, entre Julio de 2008 y Mayo de 2010. INI (Albúmina/CRP) y el estadio nutricional (Valoración Global Subjetiva-SGA) fueran evaluados. INI de riesgo fue definido como menor que 0.35. El tiempo medio de acompañamiento fue 1.6 año. Analices estadísticas fueran realizadas con el programa Stata 11.1™.**

Resultados: **Fueron evaluados 74 pacientes, con edad media de 63.4 años, la mayoría hombres (58%) e con cáncer gastrointestinal (71%). Desnutrición fue identificada en 87% de los pacientes (22% con desnutrición grave). El INI medio fue 2.67 y 54% de los individuos presentaban INI de riesgo. Durante el acompañamiento hubieran 49 óbitos (66%). El tiempo mediano de sobrevida de los pacientes con INI de riesgo fue significantemente más corto que de los pacientes con INI normal (p = 0.002). El grupo con INI de riesgo llevó 0.78 año para decaer 50%, en cuanto el grupo con INI normal llevó 2.78 año (p = 0.001). INI de riesgo y desnutrición grave fueron factores independientes de peor sobrevida. Conclusión: El INI demostró capacidad pronostica en esta amuestra y puede ser una herramienta útil, basada testes rutineros y disponibles, para evaluar pacientes con cáncer.**

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Palabras clave: *Biomarcadores. Caquexia. Estudio longitudinal. Marcadores séricos.*

Abbreviations

BMI: Body Mass Index.
CI: Confidence Interval.
CRP: C-Reactive Protein.
GPS: Glasgow Prognostic Score.
HR: Hazard Ratio.
INI: Inflammatory-Nutritional Index.
IQR: Inter Quartile Range.
NSCLC: Non Small Cells Lung Cancer.
PINI: Prognostic Inflammatory Nutritional Index.
SGA: Subjective Global Assessment.

Introduction

Mortality in cancer is closely linked to the patient's nutritional status, with one third of deaths being caused by malnutrition, and not by the disease itself[1]. Cancer cachexia is defined as a multifactorial and complex handling syndrome, which leads to weight loss based mostly on muscle mass and, consequently, to progressive functional impairment. Such condition can be divided in three stages: pre-cachexia, in which there is a weight loss of less than 5% accompanied by anorexia and metabolic changes; cachexia, with weight/muscle loss aggravation and the onset of systemic inflammation; and refractory cachexia, the final stage of the syndrome characterized by intense catabolism, non responsivity to anticancer treatment, poor functionality and a life expectancy of less than three months[2].

As cachexia progresses to irreversible stages and contributes to the death of cancer patients, it is necessary to identify this condition as early as possible. Weight loss must be assessed and observed, specially the decrease in muscle mass. Furthermore, systemic inflammation, which plays an important role in cachexia genesis and progression, should be evaluated[3], considering that it implies worsening in prognosis[4].

For that purpose, the tools that can help the identification of the nutritional and inflammatory status of the cancer patients are useful in anticancer therapy. A previous study[5] has demonstrated an association between the Inflammatory-Nutritional Index (INI = serum Albumin / serum C Reactive Protein [CRP]) and the nutritional status according to the Subjective Global Assessment (SGA)[6,7], which is used to early detect malnutrition/nutritional risk.

As INI considers an increase in CRP levels and a decrease in albumin levels in the evaluation of the systemic inflammation, it probably has some prognostic value for cancer patients, since it has already been associated with the *Glasgow Prognostic Score* (GPS)[5]. Moreover, other studies have found an association between inflammatory markers (such as Albumin and CRP) and scores based on them, and survival prognosis in cancer [4,8-15].

Therefore, the aim of this study was to perform a survival analysis and to evaluate the prognostic capacity of the INI as an independent predictor of mortality in a cohort of gastrointestinal and lung cancer patients with a 3.5 year follow-up, and whose baseline data were collected before the first chemotherapy cycle.

Methods

This survival longitudinal study consisted of cancer patients attended at the Chemotherapy Service of the Teaching Hospital of the Federal University of Pelotas-RS/Brazil. The baseline data collection occurred from July 2008 to May 2010, and the follow-up was conducted until June 2012.

Patients aged 18 years and older, diagnosed with gastrointestinal (including annex glands) or lung cancer, and receiving chemotherapy for the first time, were considered eligible. After signing a consent form, the patients had an appointment with a nutritionist. Socio-economic, disease and treatment (tumor site/stage and chemotherapy type –those gathered from the patient medical records) data were collected using standardized questionnaires. Patients had their nutritional status evaluated by the SGA[6,7] and anthropometric measurements (weight and height) collected for a further calculation of the Body Mass Index (BMI = Weight [kg] / Height[m]^2).

After the appointment, patients were conducted to the laboratory for the measurement of serum albumin and CRP and subsequent calculation of the INI[5]. For this study, INI values lower than 0.35 were determined as risk INI, considering the cut point of normality for serum albumin (3.5 g/dL) and CRP (10 mg/dL).

After 3.5 years from the baseline, phone calls were made to check the patients' conditions. When the phone contact was not possible, the government database of death records was consulted to verify whether death has occurred and when.

Data were double entered and the consistency was checked using EpiInfo™ 6.04d software. Statistical analyses were performed by Stata™ 11.1 package. For survival analyses, it was used the Kaplan-Meyer curves. Associations to death were tested with Student's t, χ^2 or Fischer's exact tests, according to the variable nature. Those variables which test presented $p < 0.20$ in univariate analysis were included in multivariate analysis by Cox Proportional Hazard regression model.

This study was approved by the Research Ethics Committee of the School of Medicine of the Federal University of Pelotas, responsible for the Hospital where it was conducted (of. 066/2006).

Results

Seventy-four patients, mean aged 63.4 ±11.9 years old, most of them male (58.1%) participated in the

Table I
Description of the characteristics of cancer patients evaluated at the Chemotherapy Service of the Teaching Hospital of the Federal University of Pelotas - RS - Brazil

Characteristic	*n*	*Frequency (%)*
Gender		
Male	43	58.1
Female	31	41.9
Tumor site		
Esophagus/Stomach	16	21.6
Colon/Rectum	33	44.6
Pancreas/Gall bladder	4	5.4
Lung	21	28.4
Tumor stage		
II	19	25.7
III	24	32.4
IV	21	28.4
Unknown	10	13.5
Chemotherapy type		
Curative	1	1.3
Neoadjuvant	23	31.1
Adjuvant	10	13.5
Palliative	40	54.1
Nutritional status (SGA)*		
Well nourished (A)	10	13.5
Suspected/moderated malnutrition (B)	48	64.9
Severe malnutrition (C)	16	21.6
*BMI***		
Under nutrition	6	8.1
Normal	43	58.1
Excessive weight (≥ 25.0 kg/m^2)	25	33.8
*Risk INI****		
Yes	40	54.1
No	34	45.9
Total	**74**	**100.0**

*Subjective Global Assessment.
**Body Mass Index.
***Inflammatory-Nutritional Index.

study. The most prevalent tumor site was colon/rectum (44.6%) followed by lung cancer (28.4%). Around 30% of the patients had stage IV disease and 54.1% received indication of palliative chemotherapy. The detailed sample's description is shown in table I.

With regard to the nutritional status, according to SGA, almost 87% of the sample had some degree of malnutrition. The mean BMI of the patients was 23.3 kg/m^2, ranging from 15.5 to 36.6 kg/m^2; only six patients (8.1%) were classified as malnourished according to this indicator, and most of them (58.1%) were eutrophic.

Serum CRP levels presented mean of 39.29 ± 48.61 mg/dL (median 13.25 IQR: 3.28; 59.3 mg/dL), while serum albumin levels had mean of 3.73 ±0.39 g/dL (ranging from 2.66 to 4.41 g/dL). The mean INI was 2.67 ± 8.08 (median of 0.27 IQR: 0.06; 1.30), with most of the sample (54.1%) presenting Risk INI (< 0.35). Table II compares the subjects characteristics according to the INI categories (risk or not).

Table II
Comparison of characteristics of the patients with risk INI (< 0.35) and normal INI

Characteristic	*Normal INI n (%)*	*Risk INI n (%)*	*P value**
Gender			**0.406**
Male	18 (41.9)	25 (58.1)	
Female	16 (51.6)	15 (48.4)	
*Age (years old)***			**0.094**
Mean ± SD	60.9 ± 11.6	65.5 ± 11.8	
*Tumor site****			**0.053**
Esophagus/Stomach	10 (62.5)	6 (37.5)	1.000
Colon/Rectum	16 (48.5)	17 (51.5)	0.357
Pancreas/Gall bladder	3 (75.0)	1 (25.0)	0.639
Lung	5 (23.8)	16 (76.2)	0.176
*Tumor stage****			**0.112**
II	11 (57.9)	8 (42.1)	
III	14 (58.3)	10 (41.7)	
IV	6 (28.6)	15 (71.4)	
Unknown	3 (45.9)	7 (54.1)	
*Chemotherapy type****			**0.024**
Curative	14 (60.9)	9 (39.1)	1.000
Neoadjuvant	7 (70.0)	3 (30.0)	0.616
Adjuvant	0 (0.0)	1 (100.0)	0.227
Palliative	13 (32.5)	27 (67.5)	0.028
*Nutritional status (SGA)****			**0.178**
Well nourished (A)	7 (70.0)	3 (30.0)	
Suspected/moderated malnutrition (B)	22 (45.8)	26 (54.2)	
Severe malnutrition (C)	5 (31.3)	11 (68.7)	
*BMI****			**1.000**
Under nutrition	3 (50.0)	3 (50.0)	
Normal	20 (46.5)	23 (53.5)	
Excessive weight (≥ 25.0 kg/m^2)	11 (45.9)	14 (54.1)	
Death			**0.007**
No	17 (68.0)	8 (32.0)	
Yes	17 (34.7)	32 (65.3)	
Total	**34 (45.9%)**	**40 (54.1%)**	

* χ^2 test.
**Student's T test.
***Fischer's Exact test.

The mean survival follow-up was 1.6 ±1.2 years, with a minimum of 0.01 years (early deaths around the baseline period) and maximum of 3.6 years. During this period, there were 49 deaths (66.2%) and, according to the bivariate analysis, its occurrence was associated to increased age (p = 0.005), tumor location (p = 0.001, lower mortality rate in colon/rectum cancer patients and higher mortality rate in pancreatic cancer), palliative chemotherapy (p = 0.001), worsening of the nutritional status according to SGA (p < 0.001) and Risk INI (p = 0.007), as shown in table III.

The subsample with Risk INI had a 50% survival decrease in 0.78 year, while the subsample of patients with Normal INI had a 50% survival decrease in 2.78 years (p = 0.001 – fig. 1), with a hazard ratio of 2.56 (CI95%: 1.41 ; 4.64) for mortality in the Risk INI group. The median survival time for the Normal INI patients was 2.33 years (IQR: 1.13; 2.86 years), while

Table III
Comparison of characteristics of the patients according to mortality

Characteristic	*Survivor n (%)*	*Deceased n (%)*	*P value**
Gender			**0.447**
Male	13 (30.2)	30 (69.8)	
Female	12 (38.7)	19 (61.3)	
*Age (years old)***			**0.005**
Mean ± SD	58.1 ± 11.4	66.1 ± 11.3	
*Tumor site****			**0.001**
Esophagus/Stomach	2 (12.5)	14 (87.5)	1.000
Colon/Rectum	19 (57.6)	14 (42.4)	0.003
Pancreas/Gall bladder	0 (0.0)	4 (100.0)	0.046
Lung	4 (19.1)	17 (80.9)	0.592
*Tumor stage****			**0.138**
II	10 (52.6)	9 (47.4)	
III	8 (33.3)	16 (66.7)	
IV	6 (28.6)	15 (71.4)	
Unknown	1 (10.0)	9 (90.0)	
*Chemotherapy type****			**0.001**
Curative	10 (43.5)	13 (56.5)	1.000
Neoadjuvant	8 (80.0)	2 (20.0)	0.053
Adjuvant	0 (0.0)	1 (100.0)	0.388
Palliative	7 (17.5)	33 (82.5)	0.025
*Nutritional status (SGA)****			**< 0.001**
Well nourished (A)	8 (80.0)	2 (20.0)	1.000
Suspected/moderated malnutrition (B)	16 (33.3)	32 (66.7)	0.009
Severe malnutrition (C)	1 (6.3)	15 (93.7)	< 0.001
*BMI****			**0.189**
Under nutrition	1 (16.7)	5 (83.3)	
Normal	12 (27.9)	31 (72.1)	
Excessive weight (≥ 25.0 kg/m^2)	12 (48.0)	13 (52.0)	
Risk INI			**0.007**
No	17 (50.0)	17 (50.0)	
Yes	8 (20.0)	32 (80.0)	
Total	**34 (33.8%)**	**49 (66.2%)**	

* χ^2 test.
**Student's T test.
***Fischer's Exact test.

Risk INI patients presented significantly poor survival time (median of 0.79 years, IQR: 0.21; 1.88. P value = 0.002 – Mann-Whitney Test).

After the Cox Proportional Hazard analysis (table IV), severe malnutrition according to SGA (p = 0.009) and Risk INI (0.003) remained as independent predictive factors for mortality. In this sample, site tumor in colon/rectum was considered a protective factor for survival.

Discussion

Several studies have proposed the assessment of prognostic factors for survival in patients with cancer and most of them were focused on inflammatory markers, isolate or combined, to form index or scores.

In their study on esophagus-gastric cancer patients, followed by a mean period of 3.5 years, Noble et al (2013) found pre-treatment serum albumin (< 3.5 g/dL) as an independent prognostic factor for the reduction of disease-free survival (p = 0.042)[8]. Of the 29 studies in gastrointestinal cancer (most of them about colorectal cancer), 26 found albumin as an independent predictive factor of survival in a systematic review of the literature concerning the prognostic value of pre-treatment serum albumin, which included studies published between January 1995 and June 2010. The same result was found in 9 of 10 articles on lung cancer, most of them in non-small cell lung tumors[11]. In a study with 51 advanced colorectal cancer patients, Read et al found a mean survival f 4 months in those with low serum albumin (<3.5 g/dL) when compared to those patients with normal serum albumin (p = 0.017)[13]. The serum albumin was also described as an independent survival predictor (HR: 0.556 IC95%: 0.313-0.986) in a study by Utech et al in which 136 men diagnosed with various types of cancer (48.5% of them with gastrointestinal or lung cancer). In addition, an increase in inflammatory markers, such as Interleukin 6 (IL6) and Tumor Necrosis Factor alpha (TNF-α), were also associated with higher mortality[9].

With regard to the inflammatory markers based index, the use of the GPS stands out in the literature. Read et al found GPS as a mortality predictor (HR: 2.27 CI95%: 1.09-4.73) while studying advanced colorectal cancer[13]. In a study with 165 cancer patients, Elahi et al reported that there was a linear reduction of the survival time with a high GPS score, both in patients with colorectal tumors (mean survival of 12.1 months for GPS = 0, 6.1 months for GPS = 1 and 1.7 month for GPS = 2 - p < 0.001) and in gastric cancer patients (mean survival of 6.1 months for GPS = 0, 3.1 months for GPS=1 and 1.6 month for GPS = 2 - p = 0.002) [14]. In a study with 56 non-small cell lung cancer (NSCLC) patients (98% staged III/IV), presenting 77% of deaths in a mean follow-up of 54 months, the GPS was a survival prognostic factor (HR: 2.10 CI95%: 1.30-3.40) [10]. Forrest et al evaluated 161 inoperable NSCLC patients and found that the combined scores of low albumin and high CRP had a prognostic value (HR: 1.70 CI95%: 1.23-2.35-p = 0.001) when compared to scores based on stage and Performance Status (HR: 1.48 CI95%: 1.12 – 1.95 – p = 0.005)[15]. In contrast, Walsh et al used the Prognostic Inflammatory Nutritional Index (PINI= [alpha 1-acid glycoprotein × CRP] divided by [albumin × prealbumin]) and did not find any prognostic value in 50 advanced cancer patients (26% of them with lung cancer); besides, it is an index based on non-routine and more expensive laboratorial tests compared to serum albumin and CRP, and is widely used in the assessment of critically ill patients[16]. The present study showed that Risk INI is an independent survival predictor and a simple scoring system based on routine and easily available laboratorial tests. A previous study has demonstrated its association to GPS[5].

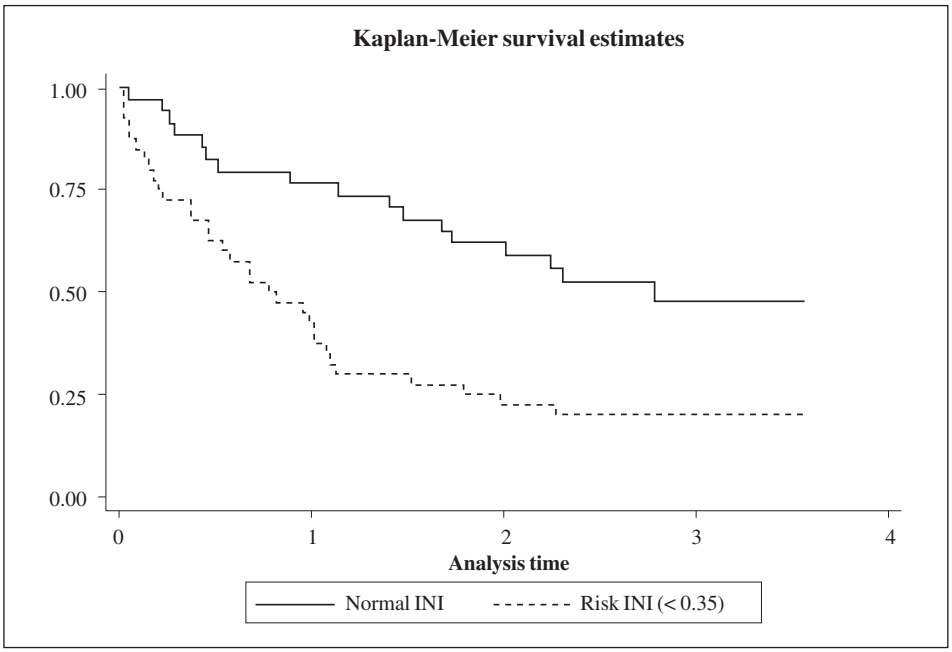

Fig. 1.—Kaplan-Meyer survival curves according to Inflammatory-Nutritional Index categories (Normal or Risk) of the gastrointestinal and lung cancer patients (p = 0.001).

Table IV
Effect of different variables on the proportional risk for poor survival (Cox Proportional Hazard Regression Model)

Variable	*Hazard ratio*	*95% CI*	*p value*
Age (as a continuous variable)	0.998	0.966-1.031	0.902
Tumor stage			
II	1.000		
III	1.076	0.405-2.861	0.883
IV	0.874	0.313-2.440	0.798
Unknown	1.487	0.486-4.545	0.487
BMI			
Under nutrition	1.000		
Normal	1.331	0.403-4.400	0.639
Excessive weight (≥ 25.0 kg/m²)	1.526	0.425-5.482	0.517
Chemotherapy type			
Curative	1.000)		
Neoadjuvant	0.218	0.025-1.877	0.166
Adjuvant	0.129	0.010-1.695	0.119
Palliative	0.330	0.040-2.698	0.301
Tumor site			
Esophagus/Stomach	1.000		
Colon/Rectum	**0.293**	**0.132-0.649**	**0.002**
Pancreas/Gall bladder	2.321	0.745-7.234	0.147
Lung	0.671	0.305-1.477	0.322
Nutritional status (SGA)			
Well nourished (A)	1.000		
Suspected/moderated malnutrition (B)	3.338	0.779-14.303	0.104
Severe malnutrition (C)	**7.453**	**1.646-33.748**	**0.009**
Risk INI			
No	1.000		
Yes	**2.845**	**1.432-5.656**	**0.003**

Bond values indicate statistically significant.

This study revealed that a worsening in nutritional status, evaluated by SGA, was associated with higher mortality and that severe malnutrition could be considered an independent predictor of mortality, with an increased rate of up to seven times when compared to well nourished patients. Read et al, also using SGA to classify the nutritional status of their advanced colorectal cancer patients, found less malnutrition (SGA "B" + "C" = 56%) than the present study, possibly because the tumor site (colorectal) affects less the ingestion, digestion and absorption of nutrients. Moreover, the presence of any degree of malnutrition was associated with a higher mortality rate (p = 0.02), with mean survival around 8 months lower than that of well nourished patients[13]. Utech et al evaluated a six-month weight loss history prior to the recruitment of the study participants (one of the SGA components) and found it to be an independent survival predictor (p = 0.002) [9]. A study conducted in the United Kingdom, using albumin < 30 g/L or BMI < 18.5 kg/m² or a recent weight loss history as criteria to define malnutrition, classified 28% of its sample (642 patients) as malnourished, being such condition an independent mortality predictor (HR: 1.43 CI95%: 1,11 – 1,85)[17]. Using BMI, which in this study was not associated with survival, Meek et al found patients with BMI lower than 20Kg/m² having twice the risk of death (HR 2.33 CI95%: 1.07 – 5.08) when compared to those with higher BMI values [10].

In his 2009 review, McMillan D.C. emphasized that the use of prognostic scores based on systemic inflammation allows the identification of patients with cachexia or those in risk of developing such condition, who are more likely to have a poorer response to treatment and shorter survival[12]. In the present study, the INI was considered an independent survival predictor, being previously associated with well known tools, such as GPS and SGA[5].

Conclusion

The INI was an independent survival predictor for this sample of cancer patients and it was associated to nutritional status. Thus, INI emerges as a possible tool for routine use in the assessment of cancer patients in and outside hospitals, with easy and quick calculation based on affordable and routinely available laboratory tests.

More studies in different cancer types may further demonstrate whether INI will be widely used in oncology.

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