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High-radiodensity skeletal index as predictor of early mortality in ovarian adenocarcinoma

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Title page

Title: **High-radiodensity skeletal index as predictor of early mortality in ovarian adenocarcinoma**

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Author contribution

Chaves GV conceived of and coordinated the study, coordinated the statistical analysis; **Bruno KA and de Paula NA** conducted collection data and statistical analysis. All authors contributed to the writing and reviewing of the paper and approved the final version.

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Abstract

Purpose: to determine the prognostic value of the quantitative and qualitative parameters of the skeletal muscle in patients with ovarian adenocarcinoma. **Methods**: In a retrospective cohort, we included patients with ovarian adenocarcinoma, enrolled between 2008-2015, who had a computerized tomography (CT) scan available within 45 days before any cancer treatment. Sociodemographic and clinical data were collected, as well as one-year survival. CT images at the third lumbar vertebra (L3) were used to assess overall skeletal muscle index (SMI), which was afterwards divided into sub-ranges of radiation attenuation: low-radiodensity skeletal muscle index (LRSMI) and high-radiodensity skeletal muscle index (HRSMI). Sarcopenia was defined when SMI was ≤ 38.9 cm^2/m^2. Kaplan-Meier method and Cox Regression evaluated one-year survival. **Results**: sarcopenia was found in 34.5% of the 139 eligible patients, although it was not associated to one-year survival. Patients in the lower quartile of the HRSMI had a shorter survival time, compared to patients in the upper quartiles ($p = 0.014$). In multiple cox regression, HRSMI was the only independent predictor of shorter survival (HR: 2.852; CI: 1.17-6.95, $p = 0.021$). **Conclusion:** these results indicate that skeletal muscle quality, specifically the amount of HRSMI, directly implies in poor prognosis of patients with ovarian adenocarcinoma. More studies are needed to understand the role of the HRSMI in cancer outcomes.

Key words: body composition, sarcopenia, myosteatosis, survival, ovarian cancer.

Introduction

In Brazil, 6150 new cases of ovarian cancer are expected in 2016/2017 [1]. Among the gynecological malignancies, ovarian cancer has the highest mortality rate and is the 6th leading cause of cancer death in women [2]. This high mortality rate is related to the late diagnosis, which occurs in 60% of cases in epithelial ovarian adenocarcinoma [3].

Malnutrition and weight loss at diagnosis are common in ovarian cancer [4,5] and these conditions are frequently aggravated during cancer treatment, which, in turn, determines unfavorable outcomes, such as higher infection rate, prolonged hospitalization, reduced quality of life and shorter survival [6 - 10].

Besides anthropometric tools are the most convenient for nutritional assessment because of their noninvasiveness, safety, and low cost when compared to other methods, they do not provide accurate information on body composition components, and are poorly associated with clinical outcomes [6]. Especially in advanced ovarian cancer, due to the large volume of tumor, ascites, edema, the isolated use of anthropometric parameters such as weight loss and body mass index should be contraindicated [11].

Computerized tomography (CT) allows the quantification of skeletal muscle (SM) and fat mass, through the measurement of a cross-sectional area of the third lumbar vertebra (L3), and has been widely used to determine body composition on the oncology setting [12], as this exam is routinely performed for diagnosis, staging, and clinical follow-up in cancer patients [13].

Retrospective studies that assessed the prognostic value of the changes in body composition in cancer patients concluded that reduced SM mass (sarcopenia), low SM attenuation and increased fat mass are independent risk factors for shorter survival [14-18], besides determining unfavorable surgical outcomes [19].

Myosteatosis, characterized by reduced muscle attenuation and increased inter- and intramuscular fat infiltration, has emerged as an independent risk factor for cancer mortality, although the pathogenesis has not yet been elucidated [20]. Nevertheless, the clinical relevance of SM quality and its relation with survival was not completely defined in the oncological context [21].

To date, studies that assess the relationship of low muscle radiation attenuation in clinical outcomes are based on comparing average muscle attenuation, rather than characterizing the extent of the SM area of low or high attenuation [11, 22, 23]. Recently, studies conducted in our group have shown that the amount of high-radiodensity skeletal muscle seems to be a better prognostic factor than the low SM attenuation or the total amount of SM [24].

Therefore, the present study aimed to determine the prognostic value of the quantitative and qualitative parameters of the skeletal muscle in patients with ovarian adenocarcinoma.

Methods

In a retrospective cohort study, we included all patients referred to a leading cancer treatment institute in Brazil from October 2008 to December 2015, who had a histopathological confirmation of epithelial adenocarcinoma ovarian cancer and who had available lumbar CT images taken up to 45 days prior to or 30 days after the first cancer treatment (surgery with curative proposal or chemotherapy). Women previously diagnosed with another type of cancer or those with synchronous tumors were excluded from the study, as well as those with low-quality CT images. The study was approved by the Ethics and Research Committee of the institution, under number 466.070/2013.

Data collection

Sociodemographic data, such as age, marital status, ethnic group, educational level, occupation, as well as information related to cancer treatment - histological subtype, staging of cancer, tumor differentiation, type of treatment performed, presence of comorbidities and date of death were collected in physical and electronic medical records and recorded in a specific form. The staging was performed based on the criteria of the International Federation of Gynecology and Obstetrics (FIGO) for gynecological cancers [25].

Assessment of body composition

For body composition analysis, CT scans of the patients' abdomen and pelvis were retrieved in Digital Imaging and Communications in Medicine (DICOM) format. Slices taken at the 3rd lumbar vertebra (L3) were analyzed by the same trained observer with the aid of the SliceOmatic software program 5.0 (Tomovision, Canada), which allows specific demarcation of different tissues, according to their radiodensity, expressed in Hounsfield Unit (HU). The boundaries between the different tissues were corrected manually when necessary.

In order to identify and quantify the overall skeletal muscle area, the reference value as described by Mitsiopoulos *et al*. [12] was used, which consider the radiation attenuation ranging from -29 to 150 HU. This area, after corrected for stature, was designated skeletal muscle index (SMI, cm^2/m^2), expressed in cm^2/m^2, and was used to classify sarcopenia, as per the cut-off point established for women ($\leq$38.9 cm^2/m^2) [26].

Then we divided the overall skeletal muscle range into two sub-ranges: the area of skeletal muscle in the range -29 to +29 HU was denominated as low-radiodensity skeletal muscle index (LRSMI, cm^2/m^2) and the area in the range +30 to +150 HU was denominated as high-radiodensity skeletal muscle index (HRSMI), representing the cross-sectional muscle area with low and high attenuation, respectively (Figure 1). It was thus possible to appraise skeletal muscle quality assuming that skeletal muscle with lower and higher attenuation represent the area with increased and reduced intramyocellular triglycerides, respectively.

Data analysis

Statistical analyses were performed on version 22.0 of the SPSS statistical package for Windows (Chicago, IL, USA). The adherence test was applied to the Kolmogorov-Smirnov normal curve in order to evaluate the symmetry of the variables´ distribution curve. The distribution of the values referred to as non-normal was identified. In the description of the sample, the data was expressed in median (range) for numeric variables, and percentage for qualitative variables. One-year survival was appraised based on the date

of the first treatment and, in the absence of death within 365 days, the cases were censored. Analysis of one-year survival was conducted using the Kaplan-Meier method. The log-rank test was used for comparison of the median survival between the two groups. The Cox multiple regression analysis was carried out according to the stepwise forward method. The magnitude of association was determined by the Hazard Ratio (HR), and the variables that showed $p \geq 0.05$ were maintained in the final model. Two-sided p values < 0.05 were accepted as statistically significant.

Results

The study population consisted of 139 eligible patients, with median age 55 (22-83) years. The most frequent histological subtype was serous adenocarcinoma and more than half of the patients had advanced cancer stage. 34.5% of the patients were identified with sarcopenia according to the SMI. The patient´s sociodemographic, clinical and nutritional characteristics are described in table 1.

In regard to the one-year survival analysis, 37 (27%) deaths were recorded within the study period. Among the clinical, sociodemographic and SM parameters evaluated, the ones that were associated with shorter survival were the type of treatment performed and the low amount HRSMI (< Quartile 3). We highlight that only two death events occurred in the group allocated in the higher quartile of HRSMI and that the presence of sarcopenia or LRSMI did not determine a shorter survival time in this population (Table 2).

Figure 2 presents the Kaplan-Meier estimates for one-year survival according to the quartiles distribution of the HRSMI. In a Cox proportional hazards regression model, after adjustment for confounding variables (comorbidities hypertension and diabetes, age, cancer stage and type of cancer treatment performed), the HRSMI below the median ($\leq 2^{nd}$ quartile) was the only independent predictor of a shorter survival time (HR: 2.852; CI 95%: 1.17 - 6.95; p=0.021).

Discussion

Malnutrition is highly incident in cancer patients and, among gynecologic tumors, ovarian cancer is the most vulnerable to significant changes in nutritional status, which in turn can be misdiagnosed when assessed by anthropometric measurements, such as weight loss and the Body Mass Index [9].

Sarcopenia has been considered a key prognostic factor in metastatic cancer [13], even though studies on ovarian cancer are scarce. Kumar *et al.* [27] found a higher prevalence of sarcopenia among 296 women with advanced epithelial ovary cancer (44.6%) than that found in the present study (34.5%). Otherwise, Prado *et al*. [28] reported lower prevalence (15%) in 325 obese patients with solid tumors.

In the present study, sarcopenia presented a statistical trend, but it was not a determinant factor in one-year survival among women with ovarian adenocarcinoma, despite its high prevalence.

Rutten *et al.* [11] assessed body composition using CT scans in 123 patients with ovarian cancer before and after the chemotherapy treatment and observed that the overall survival was not different between the patients when classified according to the median of the SMI.

A recent meta-analysis conducted with 38 studies with cancer patients with solid tumors, concluded that the reduction of SMI was associated with worse overall survival [29]. On the other hand, Antoun *et al*. [22], reported no association between sarcopenia and survival in patients with metastatic renal cancer, although low mean radiation attenuation of SMI was able to predict this outcome. Thus, based on three multicenter randomized controlled trials with 734 patients with non-small cell lung cancer, Sjoblom *et al*. [30] also observed that low muscle attenuation, but not sarcopenia, was a significant independent prognostic factor for overall survival.

These results are in accordance with our results, in which the quality of the SM was an independent predictor of early mortality in the studied population, after adjustment for confounding factors. Even though the LRSMI - representing the muscular area with increased intramyocellular fat - was not a predictor, women allocated in the lower quartiles

of HRSMI had a shorter survival time compared to those in the upper quartile, with only two deaths recorded in the last group. Such results suggest that the quality of the SM was more important than the amount of SM in predicting short-term survival.

In another cohort of 208 women with endometrial cancer conducted by our group, the HRSMI was also strongest predictor of one-year mortality, when compared to mean SM attenuation and the LRSMI. It was also associated with surgical complications and length of hospital stay in patients who underwent surgery as the first cancer treatment [24].

The interest in identifying skeletal muscle fat content has increased because of its relationship with insulin resistance, obesity, impaired physical capacity and shorter survival in different clinical conditions [31, 32, 33].

In the oncology setting, the impact of the SM quality in clinical and surgical outcomes still remains inconclusive. Some authors suggest that the low average SM attenuation is related to worse outcomes [34, 35]. Based on studies that assessed the agreement between SM attenuation and muscle lipid content [32], it is possible to make an assumption that the reduction in SM attenuation indirectly reflects the amount of fat infiltration, referred in most studies as myosteatosis [23].

Thereby, we proposed the evaluation of intramuscular fat infiltration by means of the calculation of the area of LRSMI. We believe that the calculation of the representative area of low- and high-radiodensity SM is more appropriate to characterize muscle quality than merely classifying the individual according to the average of muscle attenuation since it allows identifying the magnitude of the SM area of increased and reduced fat infiltration, respectively. Indeed, our results confirmed that a high-quality SM, representing the area of reduced intramyocellular fat, was the only independent predictor of short-term survival in an adenocarcinoma ovarian cancer cohort.

Limitations

Some limitations of the present study shall be highlighted, including its retrospective design, which caused exclusion of a great number of patients for not presenting CT scans before surgical treatment. For the same reason, it was not possible to assess other important variables related to SM quality, such as muscle strength and

performance, which have already been shown to be potential prognostic factors in oncology [36]. We also point out the need of establishing suitable cut-off points to the proposed methodology by our research group for SM quality indicators. The lack of consensus regarding myosteatosis diagnosis limits the comparison of our results with other studies.

Final considerations

We conclude that the quality of SM, specifically the amount of HRSMI, directly implies in poor prognosis in adenocarcinoma ovarian cancer. However, further investigation on the relationship between the different subranges of SM radiation attenuation and functionality during and after cancer treatment would expand the understanding of the role that different phenotypes of body composition exert in cancer prognosis.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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Figure

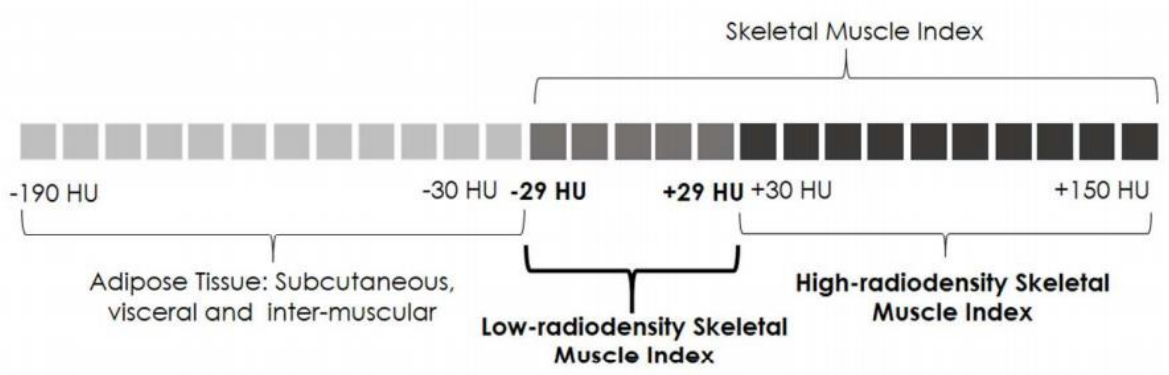

Fig 1: Skeletal muscle classification purpose according to sub-ranges of radiodensity.

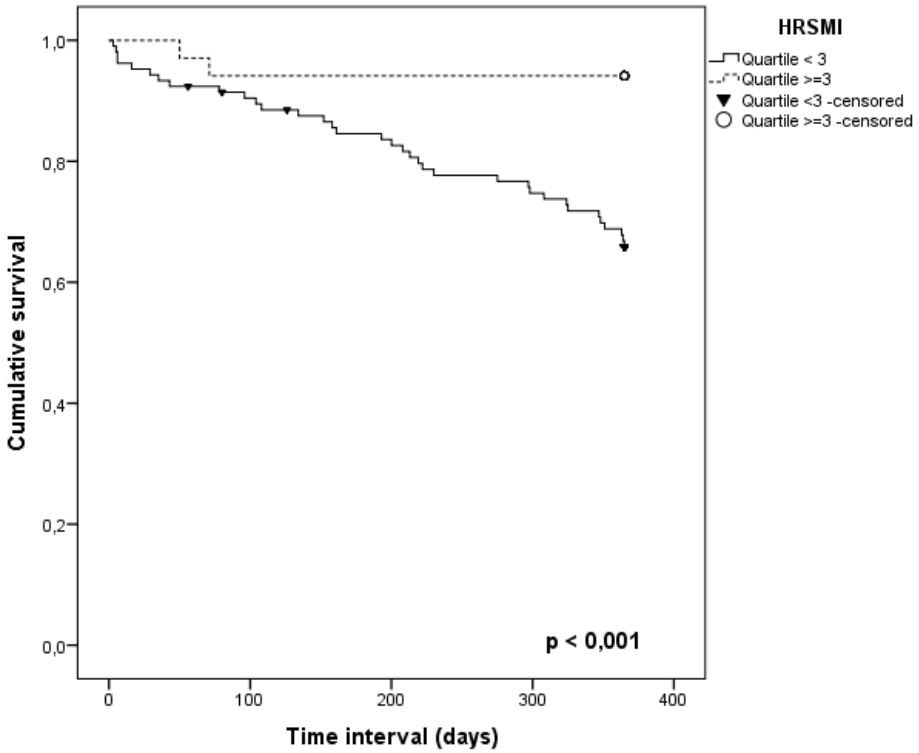

Fig 2. Kaplan Meier curve for one-year survival according to categorized distribution quartiles of the HRSMI (high-radiodensity skeletal muscle index, in range +30 to +150 HU).

Table

Table 1. Patient sociodemographic, clinical and nutritional characteristics (n=139).

Variables	**N (%)**
Age category	
<65 years	112 (80.6)
≥ 65 years	27 (19.4)
Ethnic group	
Caucasian	79 (57.2)
Mixed	46 (33.3)
Black	13 (9.4)
Educational level	
Illiterate	5 (3.6)
Elementary School	87 (62.6)
High school	36 (25.9)
Higher education	11 (7.9)
Marital status	
Single	46 (33.1)
Married	55 (39.6)
Divorced	15 (10.8)
Widowed	23 (16.5)
Occupation	
Homemaker	71 (54.2)
Employee	45 (34.3)
Retired	15 (11.5)
Histopathological characteristics	
Histologic subtype	
Serous	70 (64.8)
Mucinous	14 (13)
Endometrioid	10 (9.3)
Others	14 (13)
Degree of differentiation	
I	12 (13.6)

II	16 (18.2)
III	60 (68.2)
Stage (FIGO, 2009) [25]	
I	11 (9.2)
II	10 (8.4)
III	62 (52.1)
IV	36 (30.3)
Comorbidities	
Hypertension	56 (40.3)
Diabetes	18 (12.9)
Hypertension + Diabetes	12 (8.6)
Others*	21 (29.6)
Type of cancer tratament – 1st line	
Exclusive surgery	10 (7.2)
Chemotherapy plus surgery	80 (57.55)
Exclusive chemotherapy	49 (35.25)
LRSMI (cm^2/m^2)	
Quartile 1	15.0431
Quartile 2	18.7146
Quartile 3	23.1719
HRSMI (cm^2/m^2)	
Quartile 1	18.568
Quartile 2	22.638
Quartile 3	28.770
Sarcopenia	
Yes	48 (34.5)
No	91 (65.5)

FIGO: International Federation of Gynecology and Obstetrics; LRSMI: Low-radiodensity skeletal muscle index; HRSMI: high-radiodensity skeletal muscle index.
*Others comorbidities: dyslipidemia, renal insufficiency, heart failure, and chronic obstructive pulmonary disease.

Table 2. One-year survival analysis by Kaplan-Meier method according to the sociodemographic, clinical and nutritional characteristics of women with ovarian adenocarcinoma (n=139).

			Survival (days)		
	Women	**Events**	**Average**	**CI 95%**	**Log-Rank**
Age category					
<65 years	112	28	321.4	303.7 – 339.2	0.348
≥ 65 years	27	9	291.3	239.8 – 342.8	
Ethnic group					
Caucasian	79	20	320.9	298.7 – 343.0	0.429
Mixed	46	12	317.5	287.5 – 347.5	
Black	13	5	270.8	200.5 – 341.2	
Histologic subtype					
Serous	10	1	350.4	323.3 – 377.6	0.255
Mucinous	70	11	341.2	322.0 – 360.4	
Endometrioid	14	2	316.1	253.3 – 378.9	
Others	14	5	296.0	238.8 – 353.2	
Degree of differentiation					
I	12	1	364.9	364.8 – 365.1	0.618
II + III	76	10	349.4	335.2 – 363.7	
Stage category					
I + II	21	1	347.9	315.1 – 380.6	0.450
III + IV	98	25	328.0	311.1 – 344.9	
SMI (cm^2/m^2)					
No sarcopenia	91	20	325.8	307.1 – 344.5	0.079
Sarcopenia	48	17	296.2	260.5 – 331.8	
LRSMI (cm^2/m^2)					
<Quartile 1	33	8	317.8	282.2 – 353.4	0.244
≥ Quartile 1 e < Quartile 2	35	6	333.2	304.6 – 361.8	
≥ Quartile 2 e < Quartile 3	36	14	298.9	264.5 – 333.2	
≥ Quartile 3	35	9	313.9	274.1 – 353.8	

HRSMI (cm^2/m^2)					
<Quartile 1	36	13	285.8[a]	239.1 – 332.5	**0.014**
≥ Quartile 1 e < Quartile 2	37	12	304.2[a]	269.5 – 338,9	
≥ Quartile 2 e < Quartile 3	35	10	324.5[a]	296.3 – 352.7	
≥ Quartile 3	34	2	347.1[b]	323.0 – 371.2	
Type of cancer tratament					
Chemotherapy plus surgery	80	6	355.2[a]	345.1 – 365.3	**0.000**
Exclusive chemotherapy	49	26	268.2[b]	233.3 – 303.0	
Exclusive surgery	10	4	227.0[b]	122.0 – 332.0	

SMI: skeletal muscle index; LRSMI: Low-radiodensity skeletal muscle index; HRSMI: high-radiodensity skeletal muscle index.
Groups with different overlapping letters have significant differences in the pairwise comparison (post-hoc test).

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