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IS THE GLASGOW PROGNOSTIC SCORE - A USEFUL TOOL FOR DIAGNOSIS OF CANCER CACHEXIA?

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Abstract: ***Background:*** Cancer cachexia is characterized as a multi-factorial syndrome, identified by the continuing decline of skeletal muscle mass where nutritional support does not completely reverse the effects. Finding a cure for cachexia will impact cancer patients' worldwide, improving quality of life and potentially increasing survival in response to standard care. In turn, an accurate diagnostic tool would assist in the identification and translation of therapeutic targets to the clinic. The Glasgow Prognostic Score (GPS), is determined from combining circulating albumin and C-reactive protein (CRP) concentrations to form a score of 0 (normal) and 1 or 2 (abnormal) (albumin < 35g/L=1, and CRP> 10mg/L=1). The GPS has been used as an indicator in various cancer types, due to the presence of systemic inflammation, but not in cancer cachexia. The GPS has been validated in a wide range of clinical situation for a systemic inflammatory response so it may be beneficial in assessing the prognosis of cancer cachexia patients. ***Method / Design:*** A retrospective cohort study was conducted to assess the GPS as a valuable tool for diagnosing cancer cachexia. The relationship between BMI and the GPS was examined, along with other parameters for controls and cases. Clinical audit data was collected for 357 participants, 185 cases and 172 controls. ***Results:*** The GPS was abnormal (2; with albumin < 35 g/L and CRP > 10mg/L) in 123 (66.5%) cases and in 13 (7.6) controls. The GPS scored was also abnormal (1; with albumin < 35 g/L or CRP > 10 mg/L) in 53 (28.6%) cases and 89 (51.7%) controls. It was normal (0) in 9 (4.9%) cases and in 70 (40.7%) controls. There was a significant correlation between the GPS and a decrease in BMI as P value was 0.019. ***Conclusion:*** The GPS could be a useful indicator for the onset of cancer cachexia as advanced cancer is usually associated with a marked systemic inflammatory response which is manifested by an increase in CRP which led to a decrease in albumin. It would be beneficial to investigate if the GPS could be used for early diagnosis of cancer cachexia so it must be included in the basic assessment for all patients with cancer.

Keywords: Cancer cachexia, Glasgow Prognostic Score (GPS), C-reactive protein (CRP), Interleukin-6 (IL-6).

1. INTRODUCTION

Cancer cachexia is characterized as a multi-factorial syndrome, identified by the continuing decline of skeletal muscle mass where nutritional support does not completely reverse the effects [1]. Loss of weight in cancer cachexia patients is mainly due to reduction of adipose tissue and skeletal muscle mass and it is more than 5% or 2% in people with low BMI less than 20kg/m2[1]. Variation in metabolism which occur in cancer cachexia led to interruption in the stability between catabolism and anabolism in skeletal muscle and heart [2]. Cancer cachexia has been classified recently into three stages according to the percent of weight loss and intensity of improvement of the patient to the usable treatment [1] .The three stages of cancer cachexia include "1) Pre-cachexia, where a patient has weight loss d"5% but has not yet developed serious complications [1, 3]. 2) Cachexia, where the syndrome is progressing, with weight loss exceeding > 5% but patients can still potentially be treated [[1, 3]. 3) Refractory cachexia, the point at which the disease is no longer

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responsive to treatment or when treatment benefits are outweighed by burden and risk [1,3,4]". Cancer cachexia is the consequence of deterioration in the metabolism that leads to loss adipose tissue and skeletal muscle mass[5, 6]. Cachexia is the most prevalent cause of mortality in advance cancers [7] and accounts for up to 20% to 30% of patients deaths [2,7,8] . One of the highest causes of mortality in Australia is cancer, with more than 45,000 deaths and 123,000 new cases reported in 2014. New cases are estimated to rise to 150,000 by 2020[9]. There is an increase in morbidity and mortality among cancer cachexia patients. There is decrease in functional capability among cancer cachexia patients which lead to decrease in the quality of life and this influence their performance on everyday duty [10,11]. Cachexia decrease the effect of chemotherapy and /or radiotherapy and cause treatment toxicity[12,13]. Furthermore, cachexia may also cause an impairment in the immune response, inflammatory response, healing of the wound and changes in the metabolism [5,14].

The GPS is believed to reflect the presence of an ongoing nutritional decline (albumin) and a systemic inflammatory response (CRP) of cancer cachexia patients. Patients with a CRP > 10mg/L and decreased albumin levels < 35g/L were given a score of 2. A score of 1 was allocated to patients with only one abnormality of these two biochemical parameters. Patients with normal levels of these two biochemical measures were given a score of zero.

It has been argued that an increase in the serum level of CRP may be associated with the size of the tumor, metastasis and rate of recurrence which indicates a poor prognosis in different types of cancer [15,16].

It has also been proven that the reduction in albumin level is always secondary to an increase in CRP and indicates a poor outcome for cancer patients [17,18]. Furthermore the reduction in serum level of albumin indicates there is decrease in the percentage of lean tissue, so to examine the concentration of CRP and albumin would be beneficial in the diagnosis of cancer cachexia [17-19].

The GPS had been used in more than 60 studies for more than 30,000 patients in 13 different counties to evaluate the relation between the GPS and outcomes of cancer which include the survival, rate of the recurrence and the degree of response to treatment. These studies also evaluated the relation between the GPS and, inflammatory response and it is validated for use in different types of cancer as an independent prognostic factor [19,20], but not used in cancer cachexia patients.There are 15 studies involving more than 2,000 patients that stated an elevated GPS is associated with loss of weight, increased morbidity, and increase in pro-inflammatory cytokines and deficiency in the ability to do any activity[20].

2. HYPOTHESIS AND ENDPOINTS

We hypothesise that the GPS will be abnormal (scored 2 or 1) in cancer cachexia patients and the GPS will be either normal or will be allocated a score of 1 among patient with the same cancer type that do not have cachexia. The primary endpoint is to compare the GPS between the cases and the controls. We hypothesise that the GPS could be a beneficial tool for diagnosing cancer cachexia. The secondary endpoint is to determine whether the GPS can be a used to diagnose cancer cachexia and if there is a correlation between the GPS and a decrease in BMI in the cases.

3. MATERIALS AND METHODS

3.1. Study design and recruitment

Human Ethics approval was granted from Cairo University, National Cancer Institute (NCI), Institutional Review Board No (201516010.7), and from Deakin University Human Ethics No (2016-062).The current study used data collected from our previous case control study with one cancer cachexia patient (n=185) per one control (n=172). Patients (aged d" 18-years-old and d" 75 years) with a histological confirmed type, stage and site of the tumor. Minimum follow-up for all the participants was 6 months and the maximum was two years or death.

3.2. Cases

Eligible cases in our previous case control study were adult males or females who have a range of cancers(non-small cell lung cancer, colon, cervical or, ovarian) with weight loss e" 5% that are diagnosed with cancer cachexia. Cases were a relatively homogeneous group so to increase the chances of identifying important etiological relationships. As the NCI is a big referral centre and the patients are referred from different areas, the cases and controls should be from patients who are living in local community to NCI to avoid bias. Investigators excluded all individuals who are living outside that area as the exposure for the patients who are living in the area around NCI may be different from those who are living in other areas. Samples of cases based on cancer type and diagnosis of cachexia were approached randomly (according to a computerised random number generator).

3.3. Controls

In our previous study, investigators gave more time for precise selection of the controls who were from the same catchment population and similar in terms of age, sex, and socioeconomic, level of education and from the same community as the cases, so it is expected that both cases and controls will have the same characters. People are going to a public hospital as the NCI, for several causes (e.g. financial issue, close proximity to their home or religiousaffiliation). Eligible controls must fulfil allthe described standards for the selection of the casesexcept for the diagnosis of cancer cachexia and without weight loss so controls are free from cachexia which was the aim of our study. Selection of controls was based on the type of cancer stratification; the primary diagnosis of cancer having occurred within the previous six months with participants currently attending the oncology clinic at the NCI (hospital based); and at least four weeks after surgery, or cytotoxic chemotherapy or radiotherapy, or waiting treatment.

Eligible samples of controls are based on date and type of cancer were approached randomlyaccording to a computerised random number generator.

The investigation was a retrospective cohort study conducted to calculate the GPS (albumin <35g/ = 1 and CRP >10mg/ = 1), combined to form a prognostic score of 0 (normal) and 1 or 2 (abnormal) and to check if there is a correlation between the GPS and a drop in BMI. In addition, a variety of biochemical variables (haemoglobin, white blood cells, red blood cells, serum iron, and interleukin-6 (IL-6), liver enzymes, tumor stage and testosterone in male patients) were examined in both groups of participants to check the relationship between the GPS, these parameters, prediction of cachexia and prediction of death.

4. Statistical Method

Statistical Package for Social Sciences (SPSS) Version 22.0 was used for data management and data analysis. Descriptive statistics were performed for parametric quantitative data by mean, standard deviation and minimum and maximum of the range, as well as for categorical data by percentage and number. Analysis was performed for parametric quantitative data between two groups using independent sample *t* test, and for non-parametric quantitative data using Mann Whitney test. Analyses were done for qualitative data using Chi -Square test. Correlation between two quantitative variables was performed using Pearson's correlation coefficient and for qualitative ordinal variable by using non-parametric Spearman's rho correlation coefficient. Correlation coefficient ranges from (0-1): weak (r =0-0.24), fair (r =0.25-0.49), moderate (r =0.5-0.74), strong (r =0.75-1). Logistic regression analysis was done to detect the predictors of cachexia and death. The level of significance was taken at (*P* value < 0.05).

5. Results

In our study, both groups were matched regarding age and sex, and distribution of diagnosis was not significantly different in both groups; P value was not significant. Cases and controls were similar in gender as there were 115 female cases, 109 females in the control group, 70 male cases and 63 males in the control group. Also, there was no significant difference in age between cases and controls as mean for the cases was 50.16± 8.05 (SD) and the mean for the controls was 49.06± 7.92 (SD) and P value was 0.20. Distribution of diagnosis was also matched as there was 18 cases (9.7%) cervical cancer, 16 controls (9.3%), 28 cases (15.1%) colon cancer, 21 controls (12.2%), 75 cases (40.5%) lung cancer, 71 (41.3%) controls and 64 cases ovarian cancer (34.6%), 64 controls (37.2%) as shown in (**Figure 1)** below. Colon and lung cancers were significantly higher in males than females (in both study groups) as P value was < 0.001. Mean BMI was 23.50± 1.45(SD) for the cases and 24.71± 1.58 (SD) for the controls as shown in (**Figure 2)**. There was no significant difference between BMI of the females and males in the controls as mean BMI was 24.7±1.7(SD) for the females and 24.7±1.3 (SD) for the males and P value was 0.83. The same was for the cases as mean BMI for the females was 23.6± 1.5 (SD), mean BMI for the males in the cases group was 23.3±1.4 (SD) and P value was 0.22. There is no significant correlation between a drop in BMI and histopathological type of cancer in our study groups as mean drop in BMI was 3.49± 3.01 (SD) for adenocarcinoma, mean for serous epithelial was 3.37± 3.22 (SD), mean drop in BMI for squamous cell carcinoma was 3.90± 3.08 (SD) and P value was insignificant as it was 0.56. There was a significant correlation between smoking and site of the tumor as P value was < 0.001 as in (**Table 1)** below.

In both study groups, cases of colon and lung cancer were higher in males than females. There was no correlation either in IL-6 level or CRP level and histopathologic types in different

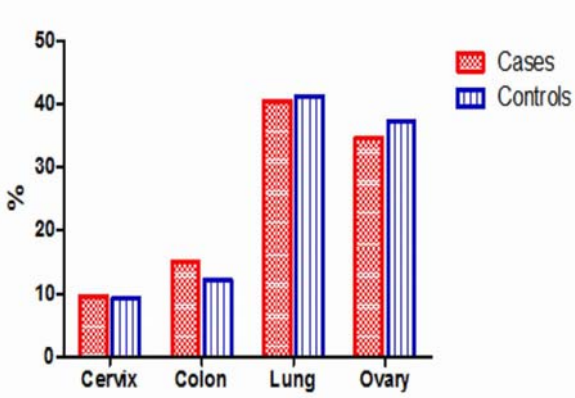

Figure-1: Cases and controls were matched in diagnosis.

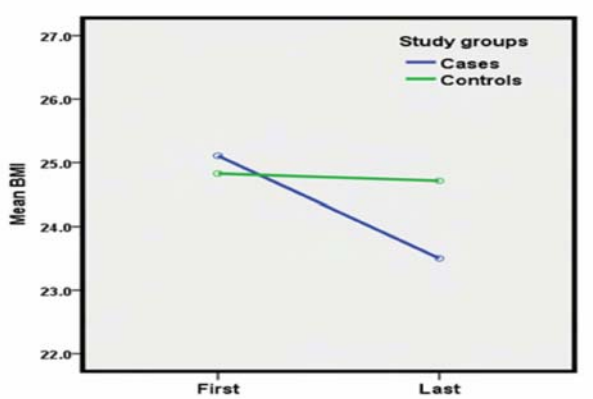

Figure-2: Mean BMI for cases and controls

Table-1: Smoking with site of the tumor

Diagnosis[a]	No	Yes
Cervix	34(100%)	0(0%)
Colon	32(65.3%)	17(34.7%)
Lung	100(68.5%)	46(31.5%)0
Ovary	128(100%)	(0%)

a. p < 0.001

Table -2: The GPS in cases and controls

	Cases	Controls	P value
GPS			
0	9(4.9%)	70 (40.7%	< 0.001*
1	53(28.6%)	89(51.7%	
2	123(68.5%)	13(7.6%	

Table-3: Correlation between the GPS 2 and parameters

	GPS 2	
	r	P value
Drop in BMI	-.172	< 0.05*
Hb	-.298	< 0.01*
IL-6	-.134	< 0.01*
Serum iron	-.176	< 0.05*

diagnosis of cancer. Testosterone levels in males were significantly higher in stage-I cancers compared to stage III cancers in the control group. Testosterone levels were also significantly higher in stage I cancerscompared to stage III in both groups combined as P value was <0.001. There was no correlation between testosterone level and histopathological type of cancer as P value was 0.09.

The GPS was abnormal (scored-2) in 123 (66.5%) cases and in 13 (7.6%) controls, the GPS scored 1 in 53 (28.6%) cases and in 89 (51.7%) in controls and *P* value was <0.01. The GPS was allocated zero in 9 cases (4.9%) and in 70 controls (40.7%) as shown in (**Table-2**). There was a significant correlation between the GPS and a drop in BMI as shown in (**Table-3**). Furthermore, there was significant correlation between the GPS and other parameters as Hb, IL-6, and serum iron in the cases as shown in (**Table-3**).

- Independent sample *t test* for parametric quantitative variables between the two groups,

- ($): Mann Whitney test for non- parametric quantitative variables between the two groups, and Chi square test for qualitative variables between the two groupsconducted to check if there is significant difference between GPS scored 2 and other different parameters in both groupsand there was significantdifference in all these parameters between the participants who are still alive and otherswho died as shown in **(Table-4)**

- Then simple logistic regression analysis for prediction of death done involving different parameters and the GPS was highly significant as odd ratio was 11.24 and P value was < 0.001 as shown in (**Table-5**).

Simple logistic regression analysis for prediction of cachexia done including different parameters and the GPS 2 was highly significant as odd ratio was 73.59, CI was 29.94-180.84 and P value was < 0.001 as shown in (**Table-6**). Multivariate analysis for prediction of cachexia (cases) as compared to no cachexia (controls) with different variables as: age, IL-6, stage of tumor, albumin, CRP, score of the GPS, and serum iron done. It revealed that GPS 2 increase likelihood of cachexia and P value was <0.001.

6. DISCUSSION

The most common cancer types at the NCI were lung cancer and colon cancer. This is similar

Table- 4: Independent sample t test for parametric quantitative variables between the two groups

	Death		P value
	No (n=243)	Yes (n=114)	
BMI	24.4±1.7	23.4±1.4	**< 0.001***
($)% decrease in BMI	2.2±2.6	6.4±1.6	**< 0.001***
WBCs	6953.1±2704.2	13251.6±2347.3	**< 0.001***
Albumin	34.8±2.7	33.2±2.5	**< 0.001***
Testosterone	437.8±153.2	276.8±119.7	**< 0.001***
($)CRP	17.5±16.6	19.2±12.3	**< 0.001***
($)IL-6	18.9±23.8	106.3±44.1	**< 0.001***
($)Lactoferrin	15.1±25.1	8.7±10.1	**< 0.001***
Iron	83.5±17.3	62.9±11.7	**< 0.001***
Tumor stage **I** **II** **III** **IV**	 91(37.4%) 54(22.2%) 31(12.8%) 67(27.6%)	 2(1.8%) 2(1.8%) 4(3.5%) 106(93%)	**< 0.001***
GPS **0** **1** **2**	 72(29.6%) 106(43.6%) 65(26.7%)	 7(6.1%) 36(31.6%) 71(62.3%)	**< 0.001***

- *($):* Mann Whitney test for non- parametric quantitative variables between the two groups
- Chi square test for qualitative variables between the two groups
- *: Significant difference at p value < 0.05

to reports in the literature of cancer cachexia prevalence [8,21].

A previous investigation by Healy evaluated 31 tools for identification of sarcopenia or cachexia, while those tools identify the risk of malnutrition, no tools contained all components for sarcopenia or cachexia [22]. In this study, the GPS was abnormal scored 1 in 28.6% , scored 2 in 66.5 % of the cases, but scored 1 in 51.7% and 2 in 7.6% of the control, that is similar to previous literature [23]. Thus an abnormal GPS may be a useful tool for diagnosis of cancer cachexia. It has been argued that in some patients with lung and pancreatic cancer, that a positive GPS is of such a serious concern that these patients should be classified as in the precachexia stage and offered multimodal therapy which could help in delaying the onset of cachexia and/or death [20]. The GPS has the advantage of being simple to measure and its components (CRP and albumin) are routinely available for all patients and can help in the diagnosis of cancer cachexia. The reduction in albumin level is secondary to increase in CRP which is an indicator of systemic inflammation, also the concentration of albumin reflects the amount of muscle tissue present which will be helpful in the diagnosis of cancer cachexia [19, 20]. A recent study have suggested that the decrease in the concentration of serum albumin which could be result from ongoing inflammation is associated with low muscle mass or increase in muscle loss in old persons [24].

7. CONCLUSION

The GPS is an inflammation-based score with its components calculated from routine laboratory measurements and could be an independent tool for the diagnosis of cancer cachexia as it reflected the presence of systemic inflammatory response together with the percentage of lean tissue and it is validated in this cohort study with a significant number of participants.

The GPS may have predictive value in diagnosing cancer cachexia, it would be beneficial if

Table -5: Simple logistic regression analysis for prediction of death

Variable	Odds ratio	95% Confidence Interval	P value
BMI	0.661	0.56-0.78	<0.001*
Hb	0.274	0.18-0.41	<0.001*
WBCs	1.001	1.001-1.001	<0.001*
Albumin	0.785	0.72-0.86	<0.001*
Testosterone	0.992	0.989-0.995	<0.001*
IL-6	1.058	1.04-1.07	<0.001*
lactoferrin	0.957	0.898-1.02	0.176
ALT	1.022	1.017-1.027	<0.001*
AST	1.031	1.024-1.037	<0.001*
Iron	0.919	0.902-0.937	<0.001*
Alkaline	1.052	1.039-1.066	<0.001*
GPS **0** **1** **2**	 3.493 11.235	 1.474-8.281 4.822-26.176	 0.005* < 0.001*
Staging **1** **2** **3** **4**	 1.685 5.871 71.985	 0.231-12.312 1.025-33.638 17.157-302.03	 0.607 0.047* <0.001*

Table -6: Simple logistic regression analysis for prediction of cachexia

Variable	Odds ratio	95% Confidence Interval	P value
BMI	0.576	0.487-0.68	<0.001*
Hb	0.079	0.046-0.135	<0.001*
RBCs	2.441	1.26-4.71	0.008*
WBCs	1.001	1.001-1.001	<0.001*
Testosterone	0.989	0.985-0.993	<0.001*
Albumin	0.551	0.48-0.63	<0.001*
CRP	1.033	1.02-1.05	<0.001*
IL-6	1.56	1.34-1.8	<0.001*
lactoferrin	0.514	0.42-0.63	<0.001*
ALT	1.92	1.81-3.12	0.008*
AST	1.8	1.2-2.69	0.004*
Iron	0.752	0.704-0.803	<0.001*
Alkaline	1.07	1.06-1.09	<0.001*
GPS **0** **1** **2**	 4.63 73.59	 2.13-10.03 29.94-180.84	 <0.001* <0.001*

the GPS could be included in the basic assessment for all patients with cancer.

Authors' contributions: AA and JK developed the study concept and initiated the project. AA, JK, WT, IA and NA provided significant input into the development of the protocol. NA did the statistical analysis of the study. Each of the authors have contributed, read and approved the final manuscript.

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