Original Article

The Clinical Significance of Pre-treatment Glasgow Prognostic Score (GPS) in Metastatic Colorectal Cancer (mCRC) Patients with FOLFIRI Plus Cetuximab or Bevacizumab as First-line Treatment: A Single Institutional Analysis

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Key Words
Pre-treatment Glasgow Prognostic Score (GPS);
Metastatic colorectal cancer (mCRC);
Overall survival (OS);
Progression-free survival (PFS);
Metastasectomy rates

Purpose. The aim of the study is to elucidate clinical significance of pre-treatment Glasgow Prognostic Score (GPS) in patients with metastatic colorectal cancer (mCRC) under bevacizumab or cetuximab plus FOLFIRI as first-line treatment.

Methods. From August 2014 to February 2020, 136 mCRC patients with FOLFIRI plus cetuximab or bevacizumab as first-line treatment were enrolled and pre-treatment values of GPS and clinicopathologic characteristics of these patients were collected. We retrospectively analyzed the correlation between pre-treatment GPS and progression-free survival (PFS), overall survival (OS), and metastasectomy rates of these enrolled patients with mCRC.

Results. Finally, we demonstrated that outcomes for mCRC patients with pre-treatment GPS = 0 group were significantly superior to those of mCRC patients with pre-treatment GPS = 1 + 2 group in median OS ($p = 0.019$) and metastasectomy rates ($p = 0.005$) but not significant difference in median PFS ($p = 0.971$).

Conclusions. Pre-treatment GPS appeared to be an appropriate prognostic indicator in median OS and metastasectomy rates in mCRC patients with FOLFIRI plus cetuximab or bevacizumab as first-line treatment.

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Colorectal cancer (CRC) is the third incidence and second cause of cancer-death globally.[1] In Taiwan, CRC is the most commonly diagnosed cancer (17,302 new cases in 2019) and the third most common cause of cancer-related deaths (6,436 deaths in 2019).[2] In newly diagnosed CRC patients, 25% are

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metastatic colorectal cancer (mCRC) cases and 25-30% of newly diagnosed CRC patients with stages I to III will eventually become mCRC.[3-6] In addition to conventional chemotherapy drugs, several agents targeting the molecular drivers of CRC pathogenesis including signaling pathways mediated by the epidermal growth receptor (EGFR) and vascular endothelial growth factor (VEGF) have been applied in such patients, with increasing survival rates.[7,8]

Despite advances in various treatment strategies, the mortality rates of CRC remain high in metastatic diseases.[9] Currently, the tumor-node-metastasis (TNM) classification is widely used for prognosis prediction in various cancers, including CRC;[10] however, the TNM staging system only reflects tumor characteristics but does not reveal patient status.[11] Accordingly, various types of evaluation scores to predict the prognosis for cancer patients have been developed, including Glasgow Prognostic Score (GPS), neutrophil/lymphocyte ratio (NLR), platelet/lymphocyte ratio (PLR), prognostic index (PI), and prognostic nutritional index (PNI).[4] Among these, the GPS is a scoring tool based on the level of pre-treatment serum C-reactive protein (CRP) and albumin, where pre-treatment GPS reflects systemic inflammatory and nutritional status before treatment.[5]

GPS is viewed as a prognostic factor for various types of cancers, including lung cancer, gastric cancer, colorectal cancer, etc.[6-8] Various reports have demonstrated that GPS seems to be used to predict overall survival (OS) independently of tumor stage and conventional scoring systems e.g. Eastern Cooperative Oncology Group (ECOG) and Karnofsky Performance Status (KPS).[12] To our best knowledge, few studies have specifically focused on pre-treatment GPS for mCRC patients; as a result, we assessed a large group of mCRC patients who were treated with chemotherapy combined with target therapy in an attempt to analyze the corrections of pre-treatment GPS and efficacies for mCRC patients.

Materials and Methods

Patients and study design

Patients were retrospectively selected from the database at Kaohsiung Medical University Chung-Ho Memorial Hospital. In this retrospective, observational study, mCRC patients with histology or imaging validating synchronous or metachronous adenocarcinoma were screened, and synchronous or metachronous mCRC cases under cetuximab or bevacizumab combined with FOLFIRI as first-line treatment were enrolled from August 2014 to February 2020. This study and final analysis were locked on March 31 2021. Exclusion criteria included (1) patients who had incomplete CRP or albumin data; and (2) patients who had malignant tumors in other organs or had suffered from other chronic inflammatory diseases causing serum elevation of CRP. The FOLFIRI with bevacizumab treatment regimen comprised bevacizumab (5 mg/kg) as a 120-min intravenous (IV) infusion on day 1, followed by irinotecan (180 mg/m^2) plus normal saline 500 mL as 4-h IV infusion and leucovorin (200 mg/m^2) plus 5-FU (2800 mg/m^2) plus 500 mL of IV normal saline for 42-48 h; this regimen was repeated once every two weeks. The FOLFIRI with cetuximab treatment regimen comprised cetuximab (500 mg/m^2) as a 120-min intravenous (IV) infusion on day 1, followed by irinotecan (180 mg/m^2) plus normal saline 500 mL as 4-h IV infusion and leucovorin (200 mg/m^2) plus 5-FU (2800 mg/m^2) plus 500 mL of IV normal saline for 42-48 h; this regimen was repeated once every two weeks.

Patients who had both serum elevation of CRP (> 10.0 mg/L) and hypoalbuminemia (< 3.5 g/dL) were allocated as GPS = 2 scores. Patients with only one of the abnormal values were allocated asGPS = 1 score, and patients who had neither were allocated GPS = 0 score (Fig. 1). Because the sample size of GPS = 2 scores is only 3 patients, so we combined GPS scores equaling 1 and 2 into one group (group 2) with the other group being GPS = 0 score (group 1). The correlation of pre-treatment GPS score and clinicopatho-

	CRP≦10.0 mg/L	CRP＞10.0 mg/L
	GPS	GPS
Albumin(g/dL) ≧3.5	0	1
Albumin(g/dL) ＜3.5	1	2

Fig. 1. The classification of Glasgow Prognostic Score (GPS).

logic characteristics including therapeutic efficacies were compared between the two groups (group 1 versus (vs.) group 2). Written informed consent was obtained from each participant, the study was conducted in accordance with the Good Clinical Practice guidelines and the Declaration of Helsinki with the protocol being approved by the Institutional Review Board of Kaohsiung Medical University Hospital [KMUHIRB-E(I)-20200036].

Blood sample analysis

All blood samples were collected and the laboratory measurements of serum values of CRP and albumin were performed before the chemotherapy and target therapy.

Clinicopathologic investigation

The clinicopathological factors were determined according to the TNM classification of malignant tumors prescribed by the AJCC 8th edition. Variables collected included sex, age, Eastern Cooperative Oncology Group (ECOG), primary lesion site, synchronous or metachronous condition, biologics, metastasectomy rates, *RAS* genotyping, *BRAF* genotyping, best response, objective response rate (ORR), disease control rate (DCR), M category of TNM staging, and pre-treatment carcinoembryonic antigen (CEA) level.

Efficacy measurement

Assessment of the tumor responses was typically performed after every six cycles of the interventional regimen with response measurements based on the Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1.[13] PFS was defined as the time from the date of enrollment until the first documentation of progression, regardless of the patient's treatment status. OS was defined as the time from the date of enrollment until the date of death or the last date of follow-up. The complete responses and partial responses were defined as ORR, and DCR was defined as confirmed complete responses, partial responses, and stable disease cases.

Statistical analysis

The analyses included patients who completed the sixth cycle of treatment and were not lost to follow-up. Continuous variables are presented as the mean ± standard deviation, and dichotomous variables as numbers and percentages. All statistical analyses were performed using SPSS v21.0 (SPSS, Chicago, IL, USA). The clinicopathological characteristics of the two groups were compared using Pearson's chi-square test; Cox regression analysis was used to estimate the hazard ratios (HRs) for all independent variables in the model; while PFS and OS were evaluated using the Kaplan-Meier method, and the log-rank test was used to compare time-to-event distributions. Statistical significance was set to $p < 0.05$.

Results

Study population and disposition

Between August 2014 to February 2020, 217 patients with a diagnosis of synchronous or metachronous mCRC who underwent bevacizumab or cetuximab plus FOLFIRI as first-line regimen were screened. Sixty patients with incomplete pre-treatment CRP or albumin data were excluded as were twenty-one patients having had malignant tumors in other organs or had suffered from other chronic inflammatory diseases causing serum elevation of CRP; finally, eligible 136 patients with mCRC who received chemotherapy and target therapy were retrospectively enrolled and analyzed (CONSORT diagram is shown in Fig. 2). These 136 patients with mCRC were then divided into two groups [group 1 (GPS = 0) and group 2 (GPS = 1 + 2)] based on their pre-treatment CRP and albumin level; finally, there were fifty-four patients with mCRC in group 1 and eighty-two patients with mCRC in group 2.

Efficacy outcomes

Patient ages ranged from 25 to 88 years with a mean of 60.60 for a total of 80 men and 56 women.

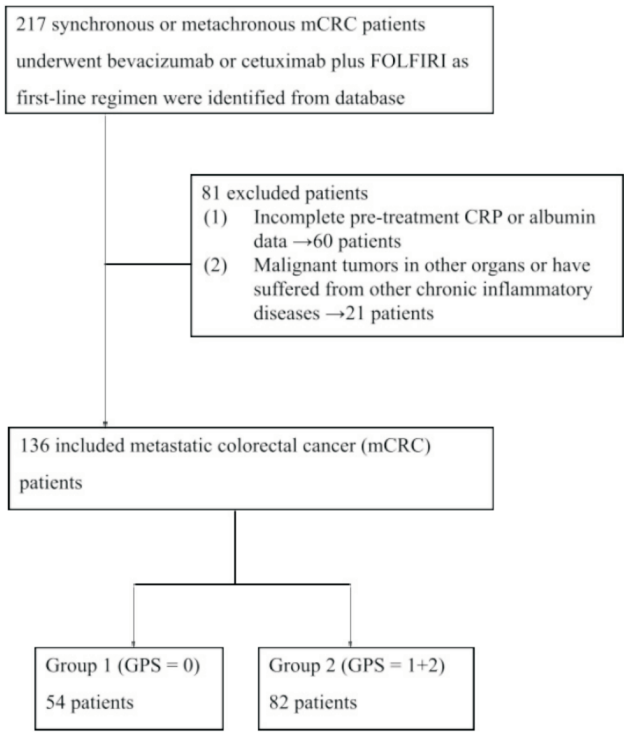

Fig. 2. CONSORT diagram.

Thirty (22.1%) were right-sided mCRC and eighty-eight (77.9%) were left-sided mCRC. The database for the final analysis was locked on March 31, 2021. At the cut-off time for analysis, the median follow-up time was 20.00 months [interquartile range (IQR), 13.25-31.75 months]. Comparison of the baseline clinicopathological features between the two groups are listed in Table 1. No significant difference in ORR and DCR was apparent in the two groups ($p = 0.089$ and $p = 0.274$ respectively, in Table 1). In addition, there is no significant difference in the M category and pre-treatment CEA level in the two groups ($p = 0.961$ and $p = 0.086$ respectively, in Table 1), although the significant difference of metastasectomy rates in group 1 (GPS = 0) than in group 2 (GPS = 1 + 2) ($p = 0.005$ in Table 1) is worth noting.

The median OS was 33.0 months vs. 20.0 months in groups 1 and 2 respectively (hazard ratio [HR], 0.589; 95% confidence interval [CI], 0.376-0.922; $p = 0.019$) (Fig. 3), with median PFS being 15.0 and 14.0 months in groups 1 and 2 respectively (HR, 0.759; 95% CI, 0.648-1.483; $p = 0.971$) (Fig. 4). The median PFS was numerically better in the study group, but the median PFS was not statistically significant.

Discussion

The novel findings of pre-treatment GPS grading in the present study are as follows: (1) Stage IV CRC patients with GPS = 0 is beneficial to OS but not to PFS (2) for metastasectomy rates, and stage IV CRC patients with GPS = 0 seemed significantly better than stage IV patients with GPS = 1 + 2.

GPS is a cumulative evaluation score composed of the serum concentrations of CRP and albumin that is used as a tool for evaluating the systemic inflammation and nutrition status and was first proposed as a prognostic indicator in patients with unresectable lung cancer in Glasgow Royal Infirmary by Forrest et al.[14] Recently, more and more studies have started to evaluate the value of GPS on malignancy diseases such as gastrointestinal tract cancer, lung cancer, cervical cancer, and other organs.[15-19] In addition, GPS has been used as a potential prognostic biomarker of nivolumab monotherapy in the third or later-line setting for advanced gastric cancer.[20,21] Additionally, the association of GPS and severe chemotherapy-related toxicities in patients with metastatic breast cancer has been reported.[22]

For the relationship between colorectal cancer (CRC) and GPS, Nozoe T. et al. reported 272 patients with CRC, and the prognosis of patients with GPS = 1 was significantly worse than that of patients with GPS = 0 while the prognosis of patients with GPS = 2 was significantly worse than that of patients with GPS = 1.[23] Kasahara K. et al. also demonstrated similar results for resectable advanced colon cancer where overall survival and recurrence-free survival of patients with GPS = 0 was better than GPS = 1 and GPS = 2.[24] In this present study, we demonstrated that the patients with GPS = 0 had significantly better median OS than those with GPS = 1 + 2. Our study showed a consistent result with the previous study that the overall survival of patients with GPS = 0 is significantly better than patients with GPS = 1 + 2, but there was no significant difference in recurrence-free survival, which was different from the study from Kasahara K. et al.

Table 1. Baseline characteristics of 136 enrolled patients with metastatic colorectal cancer under the Chi-square analysis between group 1 (GPS = 0) and Group 2 (GPS = 1 + 2)

Baseline data	N	Group 1	Group 2	*p* value
		N = 54, N (%)	N = 82, N (%)	
Sex				0.66
Male	80	33 (61.1)	47 (57.3)	
Female	56	21 (38.9)	35 (42.7)	
Age (y/o)				0.77
Mean (range)		61.1 (30-88)	60.4 (25-87)	
Age (y/o)				0.44
< 65	81	30 (55.6)	51 (62.2)	
≥ 65	55	24 (44.4)	31 (37.8)	
ECOG PS				0.669
0 + 1	132	52 (96.3)	80 (97.6)	
2	4	2 (3.7)	2 (2.4)	
Primary lesion site				0.440
Right-sided	30	14 (25.9)	16 (19.5)	
Left-sided	106	40 (74.1)	66 (80.5)	
Synchronous/metachronous				0.402
Synchronous	74	27 (50.0)	47 (57.3)	
Metachronous	62	27 (50.0)	35 (42.7)	
Biologics				0.231
Cetuximab	64	22 (40.7)	42 (51.2)	
Bevacizumab	72	32 (59.3)	40 (48.8)	
Metastasectomy				0.005
Yes	31	19 (35.2)	12 (14.6)	
No	105	35 (64.8)	70 (85.4)	
RAS genotyping				0.702
Wild type	108	42 (77.8)	66 (80.5)	
Mutant type	28	12 (22.2)	16 (19.5)	
BRAF genotyping				0.381
Wild type	128	52 (96.3)	76 (92.7)	
Mutant type	8	2 (3.7)	6 (7.3)	
Best response				0.227
Complete response (CR)	1	1 (1.9)	0 (0.0)	
Partial response (PR)	75	34 (62.9)	41 (50.0)	
Stable disease (SD)	45	15 (27.8)	30 (36.6)	
Progressive disease (PD)	15	4 (7.4)	11 (13.4)	
ORR				0.089
CR + PR	76	35 (64.8)	41 (50.0)	
SD + PD	60	19 (35.2)	41 (50.0)	
DCR				0.274
CR + PR + SD	121	50 (92.6)	71 (86.6)	
PD	15	4 (7.4)	11 (13.4)	
M category				0.961
M1a	77	30 (55.6)	47 (57.3)	
M1b	36	15 (27.8)	21 (25.6)	
M1c	23	9 (16.7)	14 (17.1)	
Pre-treatment CEA level				0.086
CEA < 5 ng/dL	51	25 (46.3)	26 (31.7)	
CEA ≥ 5 ng/dL	85	29 (53.7)	56 (68.3)	

N, number; y/o, year-old; ECOG PS, the Eastern Cooperative Oncology Group performance status; Left-sided, descending colon + sigmoid colon + rectosigmoid colon + rectum; Right-sided, cecum + ascending colon + transverse colon; Synchronous, metastatic lesions occurred initially; Metachronous, metastatic lesions occurred at least 6 months after resection of primary lesion; Biologic, means that patients received target therapy with Cetuximab or Bevacizumab; ORR, objective response rates; DCR, disease control rates ; M category, the M stage of TNM stage.

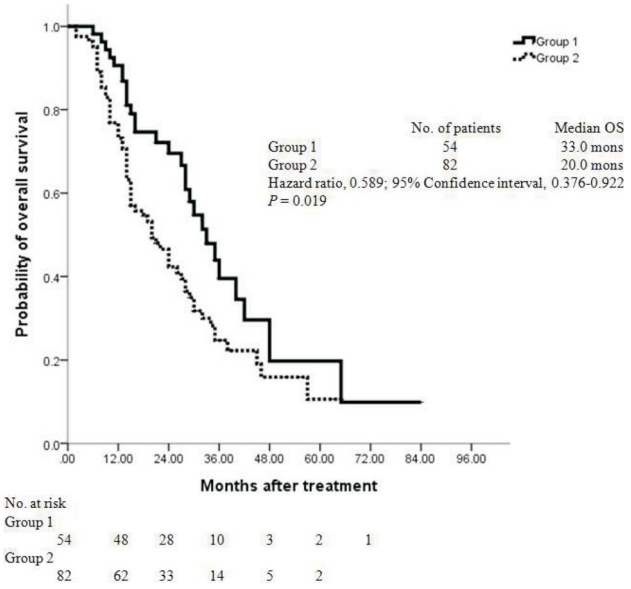

Fig. 3. The 136 patients with mCRC, including 54 patients (solid line) with GPS = 0 as the group 1 and 82 patients (dotted line) with GPS = 1 + 2 as the group 2. The group 1 was superior to the group 2 in median OS (33.0 months vs. 20.0 months, $p = 0.019$).

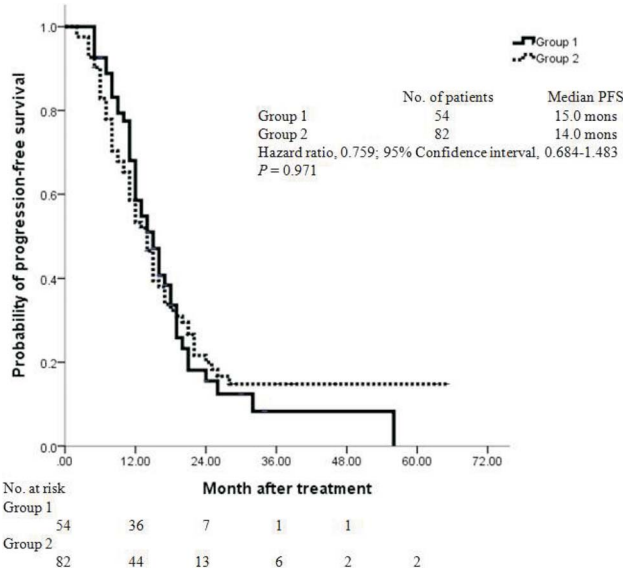

Fig. 4. The 136 patients with mCRC, including 54 patients (solid line) with GPS = 0 as the group 1 and 82 patients (dotted line) with GPS = 1 + 2 as the group 2. The group 1 was not superior to the group 2 in median PFS (15.0 months vs. 14.0 months, $p = 0.971$).

We attribute the difference to the low heterogeneity of our study group, which was confined to patients with stage IV, whereas patients with stages I-IV CRC were included in other studies;[24,25] furthermore, the probability of disease progression in patients with stage IV CRC is relatively high, and this might be a further reason why there was no significant difference in PFS in our study.

Nevertheless, our study showed that the proportion of receiving metastasectomy was significantly higher in patients with GPS = 0, which is different from the results demonstrated by Kobayashi S. et al., which showed no difference in proportion of receiving metastasectomy.[25] However, their study only took lung metastasectomy into account and there were only 15 people in the GPS = 1 + 2 group. Such a small group may make it infeasible for analysis and therefore contain statistical bias.

For the relationship between GPS and pre-treatment CEA level, though there was no statistically significant difference between GPS = 0 and GPS = 1 + 2 in our study, we could observe that the there was more proportion of CEA level greater than 5 in the GPS = 1 + 2 group (68.3%), which showed consistent result with the previous study.[26,27]

This study has several limitations. Firstly, selection bias could have been introduced as it is a single-institution, retrospective study, and secondly, there were only 3 patients with GPS = 2 in our study, so these people were combined with GPS = 1 patient into a single group. A larger sample size for GPS = 2 patients might be necessary for valid analysis future-wise.

In summary, the current results of this present study suggest that pre-treatment GPS might be an easy and useful tool to predict OS and metastasectomy rates of patients with mCRC receiving bevacizumab or cetuximab plus FOLFIRI as first-line treatment.

Conclusions

Pre-treatment GPS is a simple objective tool that reflects systemic inflammation and nutrition status and reliably predicts prognosis in advanced cancer patients. Our data supported a previously unreported association of pre-treatment GPS with OS and metastasectomy rates in patients with mCRC. However, a further prospective study is warranted to validate our

observational results.

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Authors' Contributions

All authors contributed equally to the writing of the manuscript. All authors also reviewed any revisions that were made and provided their final approval of the manuscript.

Consent for Publication

Written informed consent was obtained from the patients for the treatment. In addition, written informed consent was obtained from the patients' family for publication of this case report and any accompanying images.

Competing Interests

The authors declare that they have no competing interests.

Sources of Financial Support

Nil.

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原　著

治療前格拉斯哥預後評分在以 cetuximab 或 bevacizumab 加上 FOLFIRI 為第一線治療的轉移性結直腸癌患者的臨床意義 – 單一機構分析

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目的　本篇研究的目的以回朔性的方式以闡述治療前格拉斯哥預後評分在轉移性結直腸癌患者的臨床意義。

方法　從 2014 年 8 月至 2020 年 2 月共有 136 位接受 FOLFIRI 合併 cetuximab 或 bevacizumab 為第一線治療的轉移性結直腸癌患者被收錄到我們的研究。治療前的格拉斯哥預後評分跟病人的臨床病理特徵被檢視。我們回朔性地分析了治療前格拉斯哥預後評分跟無疾病進展存活率，整體存活率及轉移處切除率之間的關係。

結果　最後的結果顯示，治療前格拉斯哥預後評分 0 分的族群病人比治療前格拉斯哥預後評分 1 分及 2 分的族群病人有統計學上較佳的整體存活率 (p 值 = 0.019 及接受轉移病灶切除率 (p 值 = 0.005)。但在無疾病進展存活率上沒有統計上的顯著差異 (p 值 = 0.971)。

結論　治療前格拉斯哥預後評分似乎可以作為接受 FOLFIRI 及 cetuximab 或 bevacizumab 為第一線治療的轉移性結直腸癌病人在整體存活率及轉移病灶切除率上的預測因子。

關鍵詞　治療前格拉斯哥預後評分、轉移性大腸直腸癌、整體存活率、無疾病進展存活率、轉移病灶切除率。