Comparison of tumour-based (Petersen Index) and inflammation-based (Glasgow Prognostic Score) scoring systems in patients undergoing curative resection for colon cancer.

Running Title: Comparing tumour and inflammation-based scores in colon cancer

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Summary (Word Count 200)

Background: Following resection, it is important to identify colon cancer patients at high-risk of recurrence, who may benefit from adjuvant treatment. The Petersen Index (PI), a prognostic model based on pathological criteria is validated in Dukes B and C disease. Similarly, the Glasgow-Prognostic-Score (mGPS) based on biochemical criteria has also been validated. This study compares both scores in patients undergoing curative resection of colon cancer.

Methods: 244 patients underwent elective resection between 1997-2005. PI was constructed from pathological reports; mGPS was measured pre-operatively.

Findings: Median follow-up was 67 months (minimum 36 months) during which 109 patients died; 68 from cancer. On multivariate analysis of age, Dukes' stage, PI and mGPS, age (HR, 1.74, P=0.001), Dukes' stage (HR, 3.63, P<0.001), PI (HR, 2.05, P=0.010) and mGPS (HR, 2.34, P<0.001) were associated independently with cancer-specific-survival. Three-year cancer-specific-survival rates for Dukes B patients with low-risk PI were 98%, 92% and 82% for mGPS of 0, 1 and 2 respectively ($p<0.05$).

Interpretation: The high-risk PI population is small, in particular Dukes' B disease (10%). mGPS further stratifies those classified as low-risk by PI. Combining both scoring systems could identify patients who have undergone curative surgery but are at high-risk of cancer-related death, therefore guiding management and trial stratification.

Keywords: Colorectal cancer, curative resection, Petersen Index, Glasgow Prognostic Score, survival.

Introduction

Colorectal cancer is the second most common cause of cancer death in Western Europe and North America. Each year in the UK, there are approximately 35,000 new cases and 16,000 deaths attributable to this disease. Colon cancer accounts for majority of disease with approximately 22,000 new cases and over 10, 000 deaths per year [1]. Overall survival is poor; even in those who undergo resection with curative intent, only half survive five years [2].

Whilst Dukes stage is widely used to predict outcome in colon cancer, it is also recognized that the survival of patients within the staging categories is variable, particularly those with Dukes B or T3/4 N0 tumours. There is particular interest in identifying sub groups of patients with either Dukes' stage B disease or Dukes' C with only 1 positive node, who may be at relatively high or low risk respectively of developing recurrent cancer and therefore may or may not benefit from adjuvant chemotherapy [3].

Consequently, considerable effort has been directed at refining prognostic criteria. For example, numerous molecular-based factors have been evaluated [3]. Clinically useful factors should be routinely available, well standardised and validated in a variety of different patient cohorts. However, few molecular-based factors satisfy these criteria and have been incorporated into routine clinical practice. There remains a continuing need to identify clinically relevant factors that would improve the prediction of survival in patients undergoing potentially curative surgery for colon cancer.

A score based on four routinely reported pathological criteria (vascular invasion, peritoneal involvement, margin involvement and tumour perforation), the Petersen Index (PI) has been reported to predict cancer-specific outcome in Dukes' B colon cancer [4]. More recently, the PI has been validated as a prognostic score in patients undergoing potentially curative resection for both

Dukes' B and C cancer of the colon and rectum [5]. Similarly, an inflammation-based score, based on two routinely measured acute phase proteins (C-reactive protein and albumin), the Glasgow Prognostic Score (GPS) has been reported to predict cancer-specific outcome in Dukes' B colon cancer [6]. The GPS has recently been validated as a prognostic score in patients undergoing potentially curative resection for both Dukes' B and C cancer of the colon [7]. To date, the relationship between the PI and the GPS has not been examined. Moreover, the application of both scores to a single cohort of colon cancer patients has not previously been undertaken.

The aim of the present study was to compare the prognostic value of the tumour-based (Petersen Index) and inflammation-based (Glasgow Prognostic Score) scoring systems in patients undergoing resection for colon cancer.

Materials and methods

Patients with histologically proven colon cancer who, on the basis of laparotomy findings and pre-operative abdominal computed tomography, were considered to have undergone potentially curative resection between January 1997 and July 2005 in a single surgical unit at the Royal Infirmary, Glasgow were included in the study. These were consecutive, elective patients entered prospectively into a maintained database. Exclusion criteria were: (i) emergency surgery (ii) death within 30 days of surgery, (iii) clinical evidence of infection or other inflammatory conditions such as inflammatory bowel disease or rheumatoid arthritis. The tumours were staged using conventional Dukes' classification [8].

The Petersen Index was constructed from the scores allocated to the four selected pathological variables present in a tumour specimen. Intra or extramural vascular invasion, peritoneal involvement and margin involvement were allocated a score of 1 and tumour perforation was allocated a score of 2. The cumulative total is calculated and the PI considered low risk where the score is between 0 and 1 and high risk between 2 and 5 [4 5].

Blood samples were taken for routine laboratory measurements of albumin and C-reactive protein measurement prior to surgery. This is standard practice in all cancer patients in our institution. The coefficient of variation for these methods, over the range of measurement, was less than 5% as established by routine quality control procedures. The GPS was constructed as previously described [9]. Briefly, patients with both an elevated C-reactive protein (>10mg/l) and hypoalbuminaemia (<35g/l) were allocated a score of 2. Patients in whom only one of these biochemical abnormalities was present were allocated a score of 1. Patients in whom neither of these abnormalities was present were allocated a score of 0. Recently, however, the GPS has been modified based on evidence that hypoalbuminaemia, in patients with colorectal cancer without an

elevated C-reactive protein concentration, had no significant association with cancer specific survival. Therefore, patients with an elevated C-reactive protein were assigned a modified GPS score (mGPS) of 1 or 2 depending on the absence or presence of hypoalbuminaemia [6].

The provision of adjuvant treatment was at the discretion of the oncologist managing the patient following the multi-disciplinary team assessment. Therefore, all biochemical and pathological results as well as patient comorbidities were available to the oncologist in making such decisions on adjuvant treatment.

The study was approved by the Research Ethics Committee, Royal Infirmary, Glasgow.

Statistics

Grouping of the variables was carried out using standard thresholds. Univariate survival analysis was performed using the Kaplan–Meier method with the log-rank test. Multivariate survival analysis and calculation of hazard ratios (HR) were performed using Cox's proportional-hazards model. A stepwise backward procedure was used to derive a final model of the variables that had a significant independent relationship with survival. To remove a variable from the model, the corresponding P-value had to be greater than 0.05. Deaths up to August 1st 2008 were included in the analysis. Analysis was performed using SPSS software (SPSS Inc., Chicago, IL, USA).

Results

Baseline clinico-pathological characteristics and the relationship with 5 year survival rate of the patients (n= 244) who underwent curative surgery for colon cancer are shown in Table 1. The majority of patients were 65 or older (73%), were male (52%), and had Dukes' stage A/B disease (59%). Fifty-six (23%) patients received adjuvant chemotherapy. Median number of lymph nodes sampled was 14 (range 3-52) for Dukes' B tumours and 14 (range 3-34) for Dukes' C tumours. The majority of patients had no evidence of vascular invasion (67%), peritoneal involvement (74%), resection margin involvement (91%) and tumour perforation (97%) and had a low risk Petersen Index (87%). The majority of patients had C-reactive protein (51%) and albumin (83%) concentrations in the normal range and a normal mGPS (51%). Of the 40 patients with hypoalbuminaemia, 31 (78%) had an elevated C-reactive protein concentration.

The minimum follow-up was 36 months; the median follow-up of the survivors was 67 months. No patients were lost to follow up. During this period 68 patients died of their cancer and a further 41 patients died of intercurrent disease. The univariate survival analysis for baseline clinico-pathological characteristics are shown in Table 1. On univariate survival analysis of individual variables, age ($P<0.001$), Dukes' stage ($P<0.001$), vascular invasion ($P<0.001$), peritoneal involvement ($P<0.001$), resection margin involvement ($P<0.001$), tumour perforation ($P<0.005$) C-reactive protein ($P<0.001$) and albumin ($P<0.05$) were associated significantly with overall survival. Both PI ($P<0.001$) and mGPS ($P<0.001$) were associated significantly with overall survival (Table 1).

On univariate survival analysis of individual variables, age ($P<0.001$), Dukes' stage ($P<0.001$), vascular invasion ($P<0.001$), peritoneal involvement ($P<0.001$), resection margin involvement ($P<0.001$), tumour perforation ($P<0.005$) C-reactive protein ($P<0.001$) and albumin

(P<0.005) were associated significantly with cancer specific survival. On multivariate analysis of these significant variables age (HR, 1.80, 95% CI, 1.30–2.49, P<0.001), Dukes' stage (HR, 3.14, 95% CI, 1.82-5.40, P<0.001), vascular invasion (HR, 2.18, 95% CI, 1.25-3.82, P=0.006), C-reactive protein (HR, 2.09, 95% CI, 1.20-3.65, P=0.010) and albumin (HR, 2.33, 95% CI, 1.30-4.17, P=0.004) were associated independently with cancer specific survival. On multivariate analysis of age, Dukes' stage, PI and mGPS, age (HR, 1.74, 95% CI, 1.27-2.39, P=0.001), Dukes' stage (HR, 3.63, 95% CI, 2.13-6.18, P<0.001), PI (HR, 2.05, 95% CI, 1.19-3.56, P=0.010) and mGPS (HR, 2.34, 95% CI, 1.65-3.31, P<0.001) were associated independently with cancer specific survival.

Multivariate survival analysis in patients with Dukes' stage B and stage C disease is shown in Table 2. In those patients with Dukes' B stage disease, age (P<0.05), PI (P<0.001) and mGPS (P<0.01) were associated independently with cancer specific survival. In those patients with Dukes' C stage disease, age (P<0.05) and mGPS (P<0.001) were associated independently with cancer specific survival.

The relationships between the PI and mGPS and cancer-specific survival in Dukes B and C colon cancer are shown in Figures 1a, 1b and Figures 2a and 2b respectively. The three year cancer specific survival rate for patients with low risk PI and Dukes' B stage disease was 98%, 92% and 82% for mGPS of 0, 1 and 2 respectively (p<0.05; Table 3). The three year cancer-specific survival rate in all patients with Dukes' C stage disease and a low risk PI was 84%, 46% and 10% for a GPS of 0, 1 and 2 respectively (p<0.001).

Discussion

The PI was initially reported in Dukes' B colon cancers [4]. To date only one other study has validated the PI as a prognostic score in Dukes' B and C colon cancer as well as rectal cancer [5]. The results of the present study further validate the PI in a different population of patients undergoing potentially curative resection for colon cancer. Of the 244 colon cancer patients included in this study, only 17% were classified as having a high risk PI. The present PI high-risk population among Dukes' B cases was 9%; smaller than the 29% of colon cancer cases originally reported by Petersen [4], but is more comparable with the recent study by Morris and colleagues [5] who also reported 9% of Dukes' B colon cancers and rectal cancers as having a high risk PI.

The basis of these differences in the classification of high risk PI between the studies is unclear. However, it may reflect differences in case mix or variability in reporting those factors that form the PI and discriminate between Dukes' B and C cases. In the Petersen study of Dukes' B colon cancers the prevalence of venous invasion (extra and intramural) was 30%; in Morris' paper of Dukes' B and C patients with both colon and rectal cancers the prevalence of extramural venous was14% and in the present paper of colon cancers venous invasion was seen in 33% of colonic resections. In the 3 studies peritoneal involvement was seen in 42% (Petersen), 14% (Morris) and 26% (present study). The number of lymph nodes can affect the Dukes' staging and the mean number of lymph nodes harvested was 21, 11 and 14 in the 3 studies. In the present study lymph node analysis was carried out using routine pathological techniques in the Department of Pathology, Glasgow Royal Infirmary. However it is recognised that immunohostochemical staining may increase the number of lymph node metastases identified (ref). Further work is required to examine the utility of the GPS following immunohistochemical staining of apparently node-negative colon cancer. Finally a recent study from Australia reports a review of the slides by a single expert

pathologist of 82 patients reported to have Dukes' B cancer but no evidence of either venous invasion or serosal involvement. Serosal involvement and/or venous invasion were identified on review in 32% and these findings correlated with survival [10].

In spite of these drawbacks in pathology reports both the present study and that of Morris and co-workers highlight the prognostic value of the PI. In particular, given that the results of both studies were drawn from cases dissected and reported by a number of pathologists, including trainee pathologists, they are likely to be representative of 'real world' pathology reporting used to inform multi-disciplinary team meetings of high risk patients with colon cancer. Therefore, we would recommend the PI should be reported routinely in patients having undergone resection for Dukes' B colon cancer, for whom it was designed, where the hazard ratio for survival in our study was approximately 10.

The present study shows for the first time that both tumour-based (PI) and inflammation-based (GPS) scoring systems have independent prognostic value in patients undergoing potentially curative resection for colon cancer. While the PI measurement is subject to variation in reporting, the pre-operative mGPS, based on standard reliable laboratory measurements, is objective and therefore there is likely to be little variation in reporting.

It is of interest to consider how these results might be combined in a clinical context. At present, patients with Dukes' C tumours are offered adjuvant chemotherapy and those with Dukes' A tumours are not. All the relevant studies concur that the PI identifies Dukes' B patients who are at high risk and arguably these patients should also be offered chemotherapy. Morris has shown that patients with single node positive Dukes' C tumours had a better prognosis than patients with Dukes' B tumours with a PI of 1 or more. In the present study, among patients with Dukes' B tumours and Dukes' C tumours with a single positive node and a low risk PI, a high risk mGPS

indicated a statistically significant poorer prognosis when compared to patients with pathologically similar tumours who had a low risk mGPS (Table 3). Such high risk patients may therefore be thought to benefit from adjuvant chemotherapy. Based on previous work, the present study was certainly powered for Dukes B (n=127) and Dukes C (n=99) analysis but not single node positive Dukes C analysis. Therefore, further single node positive Dukes C patients are required to establish whether the PI or the mGPS have prognostic value in patients undergoing potentially curative resection for these tumours.

The utility of the PI in predicting response to chemotherapy is not, to our knowledge, known. In contrast, there is evidence that an elevated C-reactive protein of the mGPS not only identifies those patients which are increased risk of recurrent disease but also those patients who are likely to benefit from adjuvant chemotherapy [11]. Therefore, on the basis of the evidence available the mGPS should be included, together with the PI, in the post-operative multi-disciplinary assessment of patients with primary operable colon cancer and the stratification of patients entering randomised trials of adjuvant chemotherapy.

The basis of the independent relationship between an elevated mGPS prior to surgery and poor long term cancer specific survival in patients with primary operable colon cancer is not clear. A plausible explanation is that an elevated mGPS may reflect compromised cell mediated immunity since an elevated C-reactive protein and hypoalbuminaemia are associated with lymphocytopenia [12] and an impaired T-lymphocytic response in the tumour [13]. Furthermore, the presence of an elevated C-reactive protein concentration and hypoalbuminaemia have also been shown to be associated with upregulation of components of innate immune system, including complement and macrophage function [14 15]. In addition, it is known that as part of the systemic inflammatory response, there is a release of pro-inflammatory cytokines and growth factors which may promote tumour growth [16 17].

Therefore, the mGPS may reflect host responses that impact prognosis in colon cancer whereas the PI might be considered to provide prognostic information on tumour behaviour.

In summary, the results of the present study validate the use of the Petersen Index in predicting cancer specific survival in patients undergoing elective potentially curative for Dukes' B colon cancer. Furthermore the results indicate that the mGPS further stratifies those patients with Dukes' B and single node positive Dukes' C cancers, classified as low risk by the PI. The PI and the mGPS scoring systems could therefore be combined at a multidisciplinary meeting to identify those patients with colorectal cancer who have undergone potentially curative surgery but who are at high risk of cancer related death.

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Conflict of Interest

All authors declare that there are no conflicts of interest to report.

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Table 1. Clinicopathological characteristics in patients undergoing potentially curative resection for colon cancer: Univariate survival analysis.

	Patients 244 (%)	Overall 3-year survival rate % (SE)	P-value (log-rank)	Cancer 3-year survival rate % (SE)	P-value (log-rank)
Age <65 years	65 (27)	95 (3)		95 (3)	
65-74years	72 (29)	76 (5)		84 (4)	
>75years	107 (44)	61 (5)	<0.001	68 (5)	<0.001
Sex female	118 (48)	70 (4)		79 (4)	
Male	126 (52)	79 (4)	0.416	81 (4)	0.832
Dukes Stage A	18 (7)	94 (5)		100 (0)	
B	127 (52)	85 (3)		90 (3)	
C	99 (41)	58 (5)	0.001	63 (5)	<0.001
Adjuvant therapy no	88 (77)	74 (3)		81 (3)	
yes	56 (23)	77 (6)	0.028	77 (6)	0.906
Date of Surgery 1997-2001	116 (48)	77 (4)		81 (4)	
2002-2005	128 (52)	73 (4)	0.514	79 (4)	0.773
Pathological Characteristics					
Vascular invasion no	163 (67)	83 (3)		86 (3)	
yes	81 (33)	58 (5)	<0.001	67 (5)	<0.001
Peritoneal involvement no	180 (74)	81 (3)		86 (3)	
yes	64 (26)	51 (6)	0.001	64 (6)	<0.001
Margin involvement no	221 (91)	76 (3)		82 (3)	
yes	23 (9)	57 (10)	<0.001	60 (10)	<0.001
Tumour Perforation no	308 (98)	75 (3)		81 (3)	
yes	6 (2)	50 (25)	0.001	50 (25)	0.002
Biochemical Characteristics					
C-reactive protein ≤10mg/l	125 (51)	86 (4)		92 (3)	
>10mg/l	119 (49)	63 (4)	<0.001	68 (4)	<0.001
Albumin ≥35g/l	204 (83)	78 (3)		83 (3)	
<35g/l	40 (17)	58 (8)	0.001	67 (8)	0.004
Petersen Index					
Low Risk	203 (87)	79 (3)		84 (3)	
High Risk	41 (13)	54 (8)	<0.001	61 (8)	<0.001
mGlasgow Prognostic Score					
Low Risk (0)	125 (51)	86 (3)		92 (3)	
Intermediate (1)	88 (36)	68 (5)		72 (5)	
High Risk (2)	31 (13)	48 (9)	<0.001	57 (9)	<0.001

Table 2. Clinicopathological characteristics and 3 year cancer specific survival in patients undergoing potentially curative resection for Dukes B and Dukes C colon cancer: Multivariate survival analysis.

Dukes B		n=127 (%)	3 yr Survival % (SE)	Hazard ratio (95% CI)	P-value
Age	<65yr	37	100 (0)		
	65-74yr	40	92 (4)		
	>75yr	50	81 (6)	1.87 (1.05-3.34)	0.034
Sex	Female	61	90 (4)		
	Male	66	91 (4)	0.99 (0.39-2.51)	0.984
Adjuvant therapy	No	111	92 (3)		
	Yes	16	81 (10)	0.98 (0.22-4.44)	0.979
Petersen Index	Low	115	94 (2)		
	High Risk	12	58 (14)	9.61 (3.27-28.26)	<0.001
mGlasgow Prognostic Score	Low 0	62	97 (2)		
	Intermediate 1	47	87 (5)		
	High Risk 2	18	78 (10)	2.15 (1.19-3.87)	0.010
Dukes C		n=99 (%)	3 yr Survival % (SE)	Hazard ratio (95% CI)	P-value
Age	<65yr	25	88 (6)		
	65-74yr	25	66 (10)		
	>75yr	49	48 (7)	1.72 (1.08-2.75)	0.022
Sex	Female	49	62 (7)		
	Male	50	64 (7)	1.25 (0.68-2.31)	0.477
Adjuvant therapy	No	59	54 (7)		
	Yes	40	75 (7)	0.92 (0.42-2.00)	0.832
Petersen Index	Low	70	63 (6)		
	High Risk	29	63 (9)	1.16 (0.60-2.24)	0.655
mGlasgow Prognostic Score	Low 0	50	83 (6)		
	Intermediate 1	37	51 (8)		
	High Risk 2	12	24 (13)	2.80 (1.80-4.44)	<0.001

Table 3. The relationship between the low risk Petersen Index, and the mGlasgow Prognostic Score with 3-year survival (%) in patients undergoing potentially curative resection for Dukes B, single node positive Dukes C and Dukes C colon cancer.

Dukes B	Petersen Index Low Risk (n=115)	Petersen Index High Risk (n=12)
mGlasgow Prognostic Score		
Low Risk (0)	98% (n=56)	82% (n=6)
Intermediate (1)	92% (n=42)	40% (n=5)*
High Risk (2)	82% (n=17)**	0% (n=1)**
mGlasgow Prognostic Score (0-2)	94% (n=115)	58% (n=12)

Dukes C	Petersen Index Low Risk (n=70)	Petersen Index High Risk (n=29)
mGlasgow Prognostic Score		
Low Risk (0)	84% (n=39)	76% (n=11)
Intermediate (1)	46% (n=24)***	62% (n=13)
High Risk (2)	10% (n=7)****	40% (n=5)***
mGlasgow Prognostic Score (0-2)	63% (n=70)	63% (n=29)

*p<0.1, **p<0.05, ***p<0.01, ****p<0.001: Association between increasing mGPS and cancer-specific survival on univariate analysis.

Figure 1a: The relationship between low and high risk Petersen Index (from top to bottom) and cancer specific survival in Dukes B colon cancer patients (P<0.001)

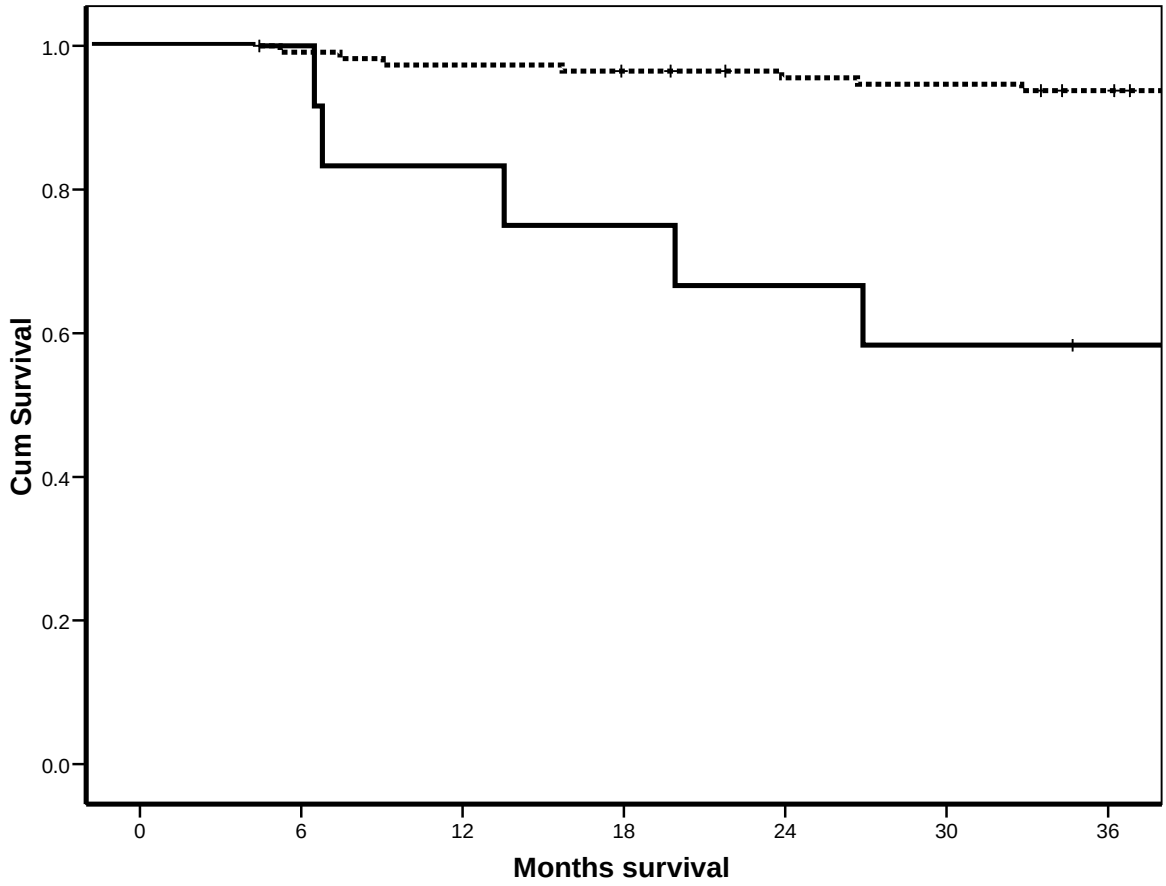

Figure 1b: The relationship between increasing mGPS (from the top to bottom) and cancer specific survival in Dukes B colon cancer patients (P<0.05)

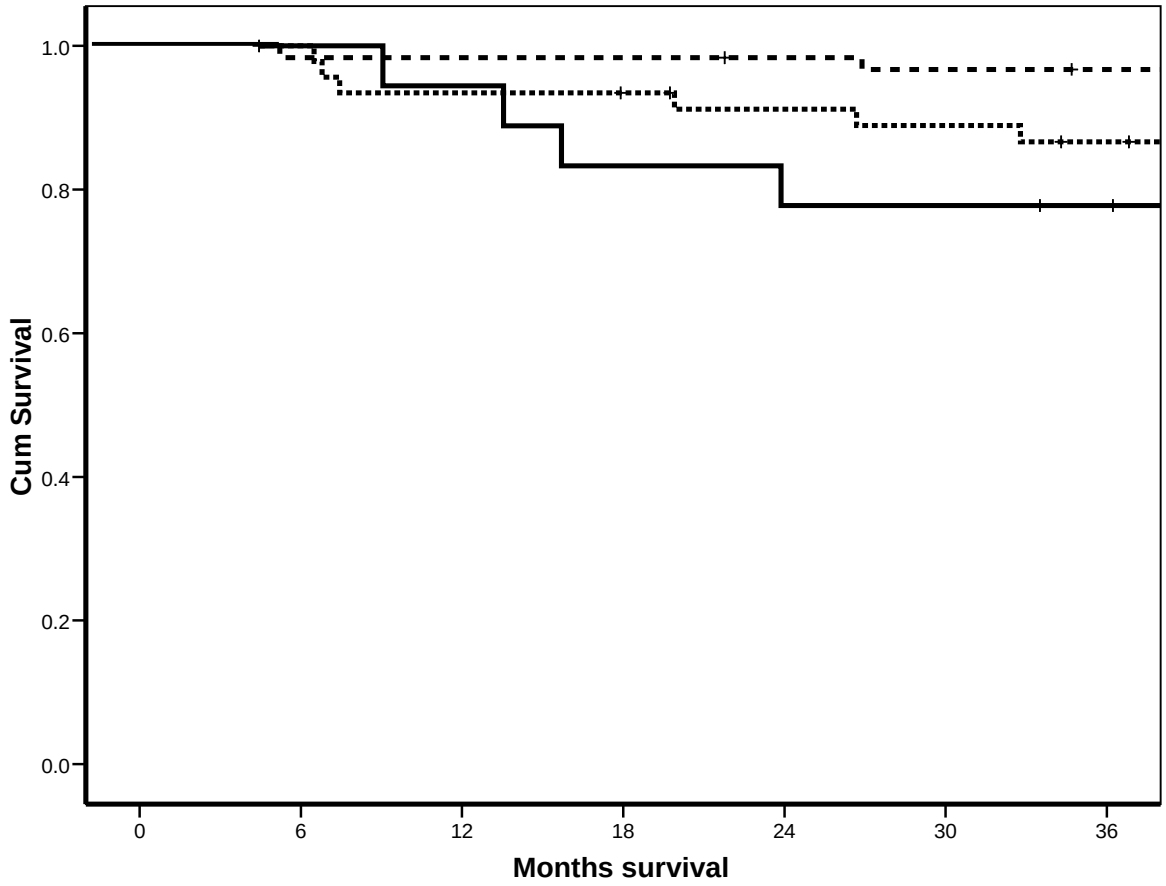

Figure 2a: The relationship between low and high risk Petersen Index (from top to bottom) and cancer specific survival in Dukes C colon cancer patients (P=0.195)

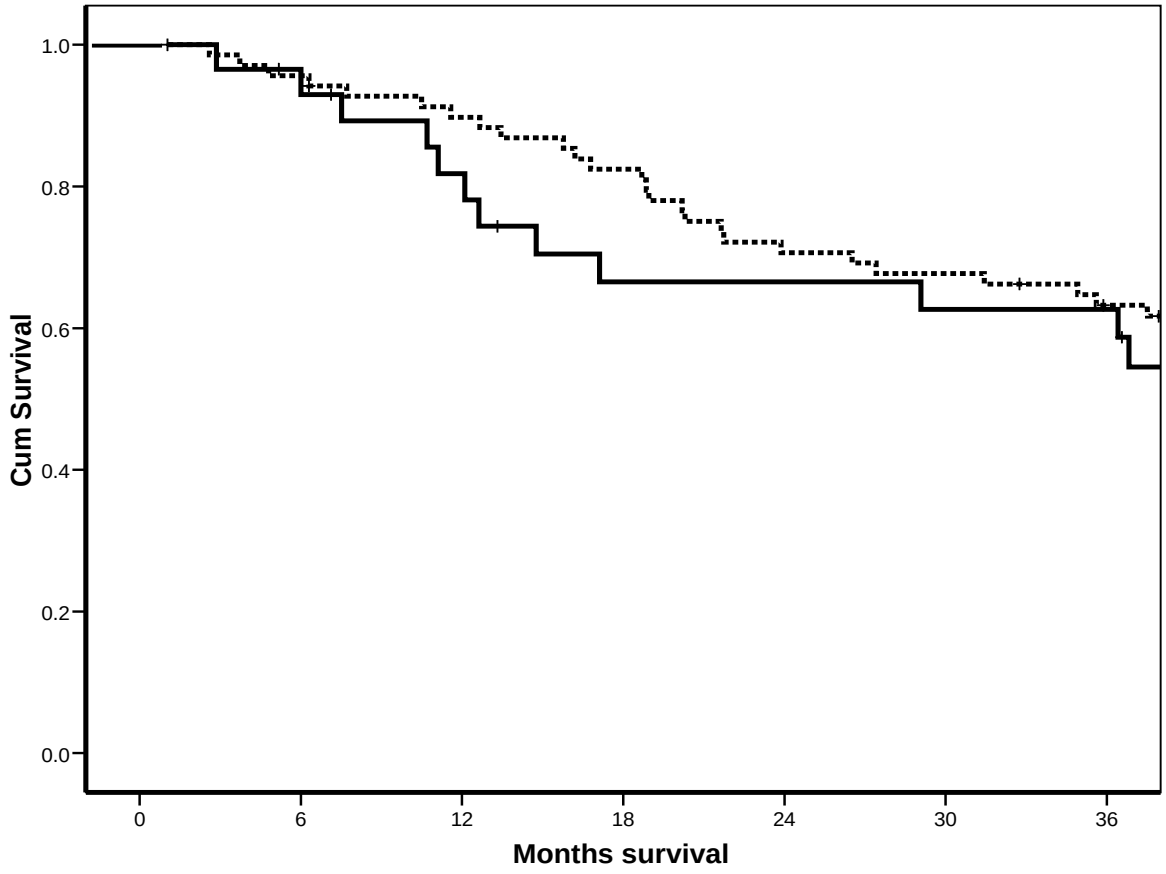

Figure 2b: The relationship between increasing mGPS (from the top to bottom) and cancer specific survival in Dukes C colon cancer patients (P<0.001)