RESEARCH ARTICLE

Araştırma Makalesi

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Assessing the Effect of Delta-PNI on Major Pathological Response After Neoadjuvant FLOT in Gastric Cancer

Neoadjuvan FLOT Alan Mide Kanserli Hastalarda Delta-PNI Değerinin Majör Patolojik Yanıt Üzerinde Etkisi

ABSTRACT

Objective

We aimed to investigate the predictive effect of prognostic nutritional index change (Delta-PNI) from initiation to completion of the neoadjuvant fluorouracil-oxaliplatin-docetaxel (FLOT) regimen on the major pathological response (mPR) in patients with non-metastatic gastric cancer.

Material and Methods

A single-center, retrospective study was conducted, screening the patients treated at Antalya Training and Research Hospital between 2019 and 2024. The difference between the PNI values prior to the initiation of FLOT and after the completion of four cycles of FLOT was calculated as Delta-PNI. The patients were dichotomised by the median of Delta-PNI value 5.4 (15,55 - 19,70).

Results

A total of 41 patients were included (n=41). The median age was 63 years (40-79) and nine patients (22%) were female. Thirteen patients (31.7%) had mPR, while five patients (12.1%) had tumor progression after neoadjuvant chemotherapy. In the univariate analysis, the high delta-PNI value (≥5.4) and low delta-PNI (<5.4) groups had similar rates of mPR [35.0% vs. 28.6%, respectively; p=0.744)]. In the multivariate analysis, the odds ratio for having mPR was 0.99, 95% CI (0.18-5.40) for patients with a higher delta-PNI value compared to those with a lower delta-PNI value (p=0.994). The other variables were also not significant: pretreatment PNI (p=0.412), sex (p=0.068), histological differentiation (p=0.248), clinical T stage (p=0.999), and N stage (p=0.256).

Conclusion

The delta-PNI was not a significant predictor of mPR. This study is the first to evaluate dynamic changes in PNI values in the literature. Future studies with larger cohorts are needed to highlight this topic.

Key Words

Gastric cancer, Prognostic Nutritional Index, Neoadjuvant treatment

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ÖZ

Amaç

Bu çalışmada, neoadjuvan florourasil-oksaliplatin-dosetaksel (FLOT) rejiminin başlanması ile tamamlanması arasındaki prognostik nutrisyon indeks farkının (Delta-PNI), metastatik olmayan mide kanseri hastalarında majör patolojik yanıt (mPR) üzerindeki öngörücü etkisini araştırmayı amaçladık.

Gereç ve Yöntemler

Bu çalışma, 2019-2024 yılları arasında Antalya Eğitim ve Araştırma Hastanesi'nde tedavi edilen hastaların tarandığı, tek merkezli, retrospektif bir çalışma olarak gerçekleştirilmiştir. FLOT rejiminin başlangıcından önceki ve dört kürün tamamlanmasından sonraki PNI değerleri arasındaki fark Delta-PNI olarak hesaplanmıştır. Hastalar, Delta-PNI medyan değeri olan 5,4'e (15,55 - 19,70) göre iki gruba ayrılmıştır.

Bulgular

Çalışmaya toplam 41 hasta (n=41) dahil edilmiştir. Medyan yaş 63 (40-79) olup, 9 hasta (%22) kadındır. On üç hasta (%31,7) mPR elde ederken, 5 hasta (%12,1) neoadjuvan kemoterapi sonrasında progresyon görülmüştür. Univariate analizlerde, yüksek Delta-PNI değeri (≥5,4) grubuyla düşük Delta-PNI (<5,4) grubunun mPR oranları benzer bulunmuştur [%35,0 vs. %28,6; p=0,744]. Multivariate analizlerde, yüksek Delta-PNI değeri olan hastaların mPR elde etme olasılığı, düşük Delta-PNI değerine sahip hastalara kıyasla 0,99 (%95 CI 0,18-5,40; p=0,994) olarak hesaplanmıştır. Diğer değişkenler de anlamlı bulunmamıştır; tedavi öncesi PNI (p=0,412), cinsiyet (p=0,068), histolojik farklılaşma (p=0,248), klinik T evresi (p=0,999) ve N evresi (p=0,256).

Sonuç

Delta-PNI, mPR için anlamlı bir prediktif belirteç olarak bulunmamıştır. Bu çalışma, literatürde PNI dinamik değişimini değerlendiren ilk çalışmadır. Gelecekte daha fazla hasta sayısı ile yapılacak çalışmalar bu konuyu aydınlatabilir.

Anahtar Kelimeler

Mide kanseri, Prognostik beslenme indeksi, Neoadjuvan tedavi

INTRODUCTION

Gastric cancer (GC) is the fifth most common malignancy worldwide, with 1,089,000 patients diagnosed yearly. It causes mortality in 769,000 patients according to GLOBOCAN, 2020 (1). Most of the GC patients are diagnosed in advanced stages which is associated with a poor prognosis (2). The median overall survival (OS) is approximately 12 months with chemotherapy (CT) (3). However, the treatment outcomes are more favorable for the localised disease for which surgery remains the principal treatment modality (4). In the last decade, the treatment strategy was shaped to its current form by FLOT4-AIO study The study protocol consisted of four cycles of neoadjuvant treatment followed by gastrectomy, and subsequently four cycles of adjuvant FLOT therapy. Achieving pCR was shown to surrogate favorable survival in patients treated with neoadjuvant therapy (5, 6). The sensititivity and specificity of 18-Fluoro-Deoxy-Glucose Positron Emulsion Tomography (18-FDG PET) remains 83% and 75%, respectively, when used in neoadjuvant therapy response evaluation (7). Moreover, pathological evaluation of tumor regression grade (TRG) in pathology specimens was found to be strongly associated with survival outcomes compared with the morphological response evaluation (8). These data suggest that there is a need in terms of response depth evaluation in addition to morphological response evaluation in gastric cancer patients receiving neoadjuvant treatment.

Gastric cancer easily leads to malnutrition because the nature of the disease is directly associated with the gastrointestinal anatomy. The obstructive pattern of GC may also contribute to the metabolic pattern of cancer-related malnutrition (9). The prognostic Nutritional Index (PNI) is an important tool to demonstrate both inflammatory and nutritional status that includes albumin level and total lymphocyte count. It has been considered to be a prognostic marker for many cancer types including lung, oesophagus and pancreatic cancer (10, 11).

Our study aimed to investigate the predictive effect of PNI change (Delta-PNI) from initiation to completion of neoadjuvant FLOT regimen on major pathological response in patients with non-metastatic gastric cancer.

MATERIAL and METHODS

Study Population

We retrospectively screened the patients with localized and locally advanced gastric cancer who were treated with neoadjuvant FLOT regimen in AntalyaTraining and Research Hospital between January 2019 and March 2024. The inclusion criteria were as follows: age over 18 years, diagnosis of gastric or gastroesophageal junction (GEJ) adenocarcinoma, and receiving four cycles of FLOT regimen in the neoadjuvant setting. Patients who received more or less than four cycles of the FLOT regimen prior to surgery and those lost to follow-up were excluded from the study. A total of 61 patients were found receiving

neoadjuvant FLOT regimen. However, 12 patients were lost to follow-up, 5 patients received more than 4 cycles and 3 patients received less than 4 cycles of the FLOT regimen for neoadjuvant treatment. The patients who had disease progression after four-cycle FLOT regimen were not excluded. Finally, there were 41 patients available in the final analysis.

This study was conducted in accordance with the Declaration of Helsinki, and ethical committee approval was obtained from the AntalyaTraining and Research Hospital Ethics Committee (Approval No: 12/19, dated August 22, 2024). The data generated in this study are available upon request from the corresponding author.

Data Collection

The clinical and pathological data of the patients were retrospectively collected from the patient follow-up files and the electronic information management system of the hospital. Age, sex, Eastern Cooperative Oncology Study Group performance status (ECOG PS), body mass index (BMI), smoking status, histological differentiation (well, moderate, or poor), tumor localization as proximal (GEJ and corpus) or distal (antrum and pylor), clinical TNM stage according to the American Joint Committee on Cancer (AJCC) 8th edition, treatment data, pre- and post-treatment laboratory test results, and postoperative pathology reports were recorded for each patient. The major pathological response (mPR) term was defined as TRG 1 or 2 (1: pCR and 2: <10% residual disease) according to pathology reports of the patients (12–14). PNI was calculated with the formulation of albumin (in grams per liter) + 0.005 X lymphocyte count (per microliter) (15). A PNI value above 50 was considered within the normal range (16). Delta-PNI was calculated as the difference between the first PNI value prior to initiation of neoadjuvant FLOT and the PNI value after the completion of four cycles of neoadjuvant FLOT.

Statistical Analysis

SPSS v26.0 was used to perform the statistical analyses. Descriptive statistics werepresented as percentages and frequency distributions. Continuous variables wereereported as mean ± standard deviation (SD), and the median value (min-max) was used. Univariate analysis of categorical variables was performed using the Chi-Square or Fischer's Exact Test. Variables with a p value <0.3 in the univariate analysis were included in the multivariate analysis. Multivariate analysis was performed using a binary logistic regression test to determine the proportional hazards affecting the mPR. Odds ratios (OR) for mPR were calculated for each variable included in the analysis with 95% confidence intervals (CI). Statistical significance was set at p value < 0.05.

RESULTS

Clinicopathological Characteristics of the Study Population

A total of 41 patients were included in the final analysis. The median age was 63 years (40-79) and nine patients (22%) were female. The ECOG PS was 0 or 1 in 92.7% of patients. Thirteen patients (31.7%) had mPR, while 5 patients (12.1%) had tumor progression after the completion of neoadjuvant chemotherapy, and three of these patients were unable to undergo definitive surgery due to metastatic dissemination after the completion of four cycles of FLOT. The pretreatment PNI value was within the normal range (≥50) in 25 (60.9%) patients and <50 in 16 patients (39.1%) (Table I). The median value for delta-PNI was 5.4 (-15,55 - 19,70). There were 21 patients (51.2%) had a delta-PNI value <5.4 and 20 patients (48.8%) had a delta-PNI value ≥5.4.

Univariate Analysis

Patients with a high delta-PNI value (≥5.4) and those with a lower delta-PNI value (<5.4) had similar rates of mPR [35.0% vs. 28.6%, respectively; p=0.744)]. Similarly, patients with normal (≥50) and low (<50) pretreatment PNI values had similar pathological responses [43.8% vs. 24.0%, respectively; (p=0.302)]. Female patients had significantly higher mPR than male patients [66.7% vs. 21.9%, respectively; p=0.018)]. Despite not being statistically significant, the p value was less than 0.3 for histological differentiation and Clinical T and N stages (Table II).

Multivariate Analysis

Multivariate analyses were performed, including the pretreatment PNI and delta-PNI values as the main research points of this study, in addition to sex, histological differentiation, and Clinical T and N stages. The OR for having mPR was 0.99 95% CI (0.18-5.40) for patients with a higher delta-PNI value compared to those with a lower delta-PNI value (p=0.994). The OR was 2.78, 95% CI (0.47-16.32) for patients in whom pretreatment PNI values were within the normal range (≥50) compared to those with low PNI level <50 (p=256). Although female sex was significantly associated with high rates of mPR compared to male sex in the univariate analysis, there was no significant effect on mPR in the multivariate analysis [OR 0.19, 95% CI (0.03-1.12), (p=0.068)]. Moreover, neither clinical T nor N stage was a significant determinant of mPR in the multivariate analysis (Table III).

Table I. Clinicopathological Characteristic of the Study Population

		n	%
Sex			
	Female	9	21.9
	Male	32	78.1
Age			
	≥50	35	85.4
	<50	6	14.6
ECOG PS			
	0-1	38	92.7
	2	3	7.3
Smoking History			
	Never Smoker	25	60.9
	Ever Smoker	16	39.1
BMI (kg/m^2)			
	≥25	19	46.3
	<25	22	53.7
Tumor Localisation			
	Proximal	26	63.4
	Distal	15	36.6
Histologic Differantiation			
	Good	2	4.9
	Moderate	23	56.1
	Poor	16	39.0
T Stage			
	1	0	0.0
	2	5	12.2
	3	29	70.7
	4	7	17.1
N stage			
	0	5	12.2
	1	16	39.1
	2	14	34.1
	3	6	14.6
Pre-treatment PNI			
	≥50	16	39.1
	<50	25	60.9
Post-treatment PNI			
	≥50	7	17.0
	<50	34	83.0
Pathological Response to Neoadjuvant FLOT			
	Complete or Major Pathological Response	13	31.7
	Minimal Response or Non-Responders	23	56.1
	Progression	5	12.2

BMI: Body Mass Index, ECOG PS: Eastern Cooperative Oncology Study Group Performance Score, FLOT: Fluoroucracil-Oxaliplatin-Docetaxel, PNI: Prognostic Nutritional Index

Table II. Univariate Analysis of Clinicopathological Factors As Predictors of Major Pathological Response

	Major Pathological Response Yes (n=13) n, (%)	No (n=28) n, (%)	p Value
Age (years)			1.000
<50	2 (33.3)	4 (66.7)	
≥50	11 (31.4)	24 (68.6)	
Sex			**0.018**
Male	7 (21.9)	25 (78.1)	
Female	6 (66.7)	3 (33.3)	
ECOG PS			0.693
0-1	12 (31.5)	26 (68.5)	
2	1 (33.3)	2 (66.7)	
BMI (kg/m²)			0.737
<25	6 (32.0)	16 (68.0)	
≥25	7 (36.8)	12 (63.2)	
Smoking Status			1.000
Never Smoker	8 (32.0)	17 (68.0)	
Ever Smoker	5 (31.3)	11 (68.7)	
Tumor Localisation			0.305
Proximal	10 (38.4)	16 (61.6)	
Distal	3 (20.0)	12 (80.0)	
Histological Differantiation			0.187
Low-Moderate	10 (40.0)	15 (60.0)	
High	3 (18.8)	13 (81.2)	
Clinical T Stage			0.077
1 - 3	13 (38.2)	21 (61.8)	
4	0 (0,0)	7 (100.0)	
Clinical N Stage			0.181
0-1	9 (42.9)	12 (57.1)	
2-3	4 (20.0)	16 (80.0)	
Pretreatment PNI Value			0.302
<50	6 (24.0)	19 (76.0)	
≥50	7 (43.8)	9 (56.2)	
Delta-PNI*			0.744
<5.40	6 (28.6)	15 (71.4)	
≥5.40	7 (35.0)	13 (65.0)	

BMI: Body Mass Index, ECOG PS: Eastern Cooperative Oncology Study Group Performance Status, PNI: Prognostic Nutritional Index
*: Median cut-off value of Delta PNI is 5.40

Table III. Multivariate Analysis of Clinicopathological Factors As Predictors of Major Pathological Response

Reference	Risk Factor	OR (%95 CI)	p Value
Sex			0.068
Ref. Female	Male	0.19 (0.03-1.12)	
Histological Differentaiation			0.248
Ref. Well- Moderate Diff.	Poor Diff.	0.33 (0.05-2.16)	
Clinical T Stage			0.999
Ref. T1-3	T4	0.00 (0.00-NA)	
Clinical N Stage			0.412
Ref. N0-1	N2-3	0.49 (0.09-2.68)	
Pretreatment PNI			0.256
Ref. <50	≥50	2.78 (0.47-16.32)	
Delta-PNI			0.994
Ref. <5.4	≥5.4	0.99 (0.18-5.40)	

CI: Confidence Interval, PNI: Prognostic Nutritional Index, Ref: Reference, OR: Odds ratio for having major pathological response

DISCUSSION

Nutritional status is the balance of intake, absorption, and use of nutrients with physiological and pathological status in the body. The balance usually changes negatively in cancer patients, resulting in malnutrition (17). Malnutrition is very common in gastric cancer patients and causes metabolic, endocrine, neuroendocrine, and immune dysfunctions (18). It is expected that tumor shrinkage with neoadjuvant treatment may result in an improved nutritional balance. PNI is widely considered to be a dynamic indicator of both immune and nutritional status, including gastric cancer patients (19, 20). However, we demonstrated that both pretreatment PNI and delta-PNI values were not independent predictors of mPR in gastric cancer patients who received four cycles of neoadjuvant FLOT.

Nutritional biomarkers and gastric cancer outcomes at the early stages of the disease have been evaluated in many studies. Previously, both albumin level and lymphocyte count were associated with mortality in cancer patients (21). These markers are generally measured in all patients and are accessible and easy markers with low costs that raise attention in PNI. In a study performed on 689 patients, Wang et al. showed that preoperative fibrinogen level and PNI (FPNI) were significantly associated with tumor volume and prognosis (22). Shen et al. reported and validated that the preoperative PNI value is an independent prognostic biomarker for survival in 525 gastric cancer patients at stage 1-3. However, over 75% of the patients in their study did not receive neoadjuvant chemotherapy (23). Another study investigating a novel score composed of PNI and IgM found that lower values of the novel PNI-IgM score correlates with reduced survival rates in 340 gastric cancer patients having a curative surgery (24). In contrast to these studies, Yun JH et al. recently showed that none of the nutritional indexes including PNI was signficantly determining the death risk in stage 2-3 gastric cancer patients (25). However, their study was performed on patients receiving adjuvant XELOX regimen, rather than neoadjuvant FLOT. The results of these studies were not consistent with those of our study. Nevertheless, no studies have directly assessed the delta-PNI value or the change in any nutritional index from the initiation of neoadjuvant treatment to the preoperative period.

Pretreatment and repetitive evaluations are necessary for the risk of malnutrition in cancer patients for an appropriate intervention with nutritional support (26). Even the PNI value was not calculated, many studies have demonstrated that nutritional support may avoid weight loss, correct any nutritional deficiency, heal the immune response, and preserve functional capacity, resulting in better outcomes in gastric cancer patients (27, 28). Nevertheless, our data did not include the proportion of patients diagnosed with malnutrition or nutritional support.

Study Limitations

The main limitation of our study was the number of patients included. The inclusion of more patients could have influenced the results of the present study. Moreover, investigating other laboratory test results besides the PNI, such as fibrinogen or IgM, could have strengthened the results of this study. The retrospective and single-center design is another limitation considering the inevitable patient selection bias. However, this is the first study to investigate the dynamic change in PNI values for early stage gastric cancer patients.

CONCLUSION

The PNI is a promising marker according to previous studies. Rather than a spot measurement of PNI, assessing the PNI change during the treatment period may be more informative for treatment efficacy and outcomes, although our study did not demonstrate a significant effect on pathological response. Future studies with a comprehensive design and a larger number of patients may improve the results on this topic.

Ethics Committee Approval

This research complies with all the relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration, and has been approved by Antalya Training and Research Hospital Ethical Committee (Approval Number: 12/19, August 22, 2024).

Informed Consent

All the participants' rights were protected and written informed consent was not obtained due to retrospective design of the study.

Author Contributions

Concept – H.G.G.; Design – H.G.G.; Supervision – B.Ö.; Resources – H.G.G., B.Ö.,; Materials – H.G.G; Data Collection and/or Processing – H.G.G., B.Ö.; Analysis and/or Interpretation – B.Ö.; Literature Search - H.G.G., B.Ö.; Writing Manuscript - H.G.G.; Critical Review - B.Ö.

Conflict of Interest

The authors have no conflict of interest to declare.

Financial Disclosure

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