Experimental
&
Clinical Article

Utilizing the Prognostic Nutritional Index to Predict Chemotherapy Toxicities in Ovarian Cancer Patients: Long-Term Tertiary Center Experiences

Secil TASHAN[1], Alperen AKSAN[2], Ayse GULEN ERTURUN[3], Nurettin BORAN[4], Ayse Sinem DURU COTELI[5], Yaprak USTUN[6]

Bursa Türkiye

ABSTRACT

OBJECTIVE: Our aim was to clearly evaluate the Prognostic Nutritional Index's ability to predict chemotherapy-induced toxicity in ovarian cancer patients undergoing platinum-based chemotherapy.

STUDY DESIGN: This retrospective cohort study of 158 patients with epithelial ovarian cancer treated with carboplatin-paclitaxel after surgery at a university hospital from 2010 to 2020 decisively investigates the Prognostic Nutritional Index (PNI) as a predictor of chemotherapy-related toxicities. PNI was calculated using pre-treatment serum albumin levels and lymphocyte counts.

RESULTS: The findings clearly demonstrate that patients with a PNI ≤34.10 experienced higher overall and severe hematologic toxicities compared to those with a higher PNI. Dose reductions and treatment delays were markedly more frequent in the low PNI group.

CONCLUSION: This study establishes that PNI is a valuable tool for assessing patient risk, though further validation will enhance its clinical utility.

Keywords: Cancer; Chemotherapy; Hematologic; Nutritional index; Ovarian personalized medicine; Prognostic toxicity

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[1] *University of Health Sciences Bursa Higher Education and Research Hospital, Department of Obstetrics and Gynecology, Bursa, Türkiye*
[2] *Gaziosmanpasa Education and Research Hospital, Department of Obstetrics and Gynecology, Istanbul, Türkiye*
[3] *Golcuk Private Medar Hospital, Department of Obstetrics and Gynecology, Kocaeli, Türkiye*
[4] *Etlik City Hospital, Department of Gynecology Oncology, Ankara, Türkiye*
[5] *Hacettepe University Faculty of Medicine, Department of Gynecology Oncology, Ankara, Türkiye*
[6] *Izmir City Hospital, Department of Obstetrics and Gynecology, Izmir, Türkiye*

Address of Correspondence: *Ayse Gulen Erturun*
Gölcük Private Medar Hospital,
Department of Obstetrics and
Gynecology, Kocaeli, Türkiye
gerturun@yahoo.com

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ORCID IDs of the authors: *ST:0000-0002-0248-7225*
AA:0000-0001-7623-3589 *NB:0000-0002-0367-5551*
ASDC:0000-0002-6558-7549 *AGE:0000-0003-0756-2463*
YU:0000-0002-1011-3848

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Introduction

Ovarian cancer remains a leading cause of death among gynecological malignancies. Epithelial ovarian cancers make up over 90% of these cases. Each year, ovarian cancer causes about 125,000 deaths and affects around 200,000 women worldwide (1). Because there are no early symptoms, most patients receive a diagnosis only at an advanced stage. Despite many studies on different treatment options, the standard approach is still primary cytoreductive surgery followed by immediate platinum-based chemotherapy (2). However, many patients cannot tolerate platinum-based and other cytotoxic chemotherapies because of drug-related toxicities. This problem is especially severe among geriatric patients. If clinicians could predict toxicity at the start of treatment, they could better assess risks and benefits for the patient and take necessary precautions in advance. This might ultimately improve clinical outcomes. Several tests have been tested, mostly in geriatric patients, but a practical, simple method for routine use has not yet been established (3).

Onodera and colleagues first introduced the Prognostic Nutritional Index (PNI) to predict nutritional and immune status in patients undergoing gastrointestinal surgery (4). PNI uses serum albumin level and lymphocyte count from peripheral venous blood samples. The formula is: '10× serum albu-

min (g/dL) + 0.005× lymphocyte count (mm³)' (4). This index reflects both nutritional and inflammatory status. It has been used to predict postoperative complications and prognosis in different malignancies (5,6). In studies of advanced ovarian cancer, a higher preoperative PNI score was associated with better overall survival, longer disease-free survival, lower FIGO stage, better response to platinum-based therapy, lower CA125 levels, and less ascites (7).

In addition, a significant association between pre-treatment PNI levels and hematologic toxicity was observed in esophageal cancer patients receiving chemotherapy or chemoradiotherapy with cisplatin and 5-fluorouracil (8). However, there are no studies in the literature investigating the use of PNI to predict chemotherapy toxicities in gynecologic cancers. Therefore, the aim of this study is to investigate the relationship between pre-chemotherapy PNI values and treatment-related toxicities in ovarian cancer patients, addressing a current gap in knowledge and potentially offering a practical tool for risk stratification.

Material and Method

Study Design: This retrospective cohort study was conducted at the chemotherapy unit of Health Sciences University Etlik Zubeyde Hanim Women's Health Training and Research Hospital. The study included patients with epithelial ovarian cancer who received paclitaxel-carboplatin after primary surgery from December 1, 2010, to December 1, 2020. All such patients in our gynecologic oncology clinics during this period were selected retrospectively from hospital records.

A total of 158 patients were included in the study after their hospital and chemotherapy records were reviewed, and eligibility criteria were met. The study included patients diagnosed with epithelial ovarian cancer who received first-line treatment with the same doses of paclitaxel-carboplatin, underwent surgery at our clinic, and received six cycles of chemotherapy. Exclusion criteria included neoadjuvant chemotherapy, the presence of another malignancy (synchronous and metastatic tumors), treatment for recurrent ovarian cancer, and failure to complete six cycles of chemotherapy for reasons other than toxicity (such as platinum-refractory disease, continuation of treatment at another center, or death).

Data collection: Blood samples were collected from patients within one week of starting chemotherapy. The researcher completed the epithelial ovarian cancer chemotherapy toxicity form based on the inclusion and exclusion criteria. The form had demographic characteristics, medical information, and post-treatment details from hospital records, patient charts, and chemotherapy forms. Chemotherapy toxicities were classified according to the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. All participants gave informed consent. The study followed the Declaration of Helsinki. Ethics committee approval was obtained on December 30, 2020, with approval number 2020/185.

Statistical analysis

The study's sample size was calculated with the G*Power 3.1.9.6 program. PNI values from patients with grade 0-2 and grade 3-4 hematologic toxicity in earlier studies were compared with a t-test (9,10). The significance level was $p < 0.01$, and the statistical power was 95%. The required sample size was 76. Data were analyzed with IBM SPSS Statistics version 27.0. Normality was checked by the Kolmogorov-Smirnov test. Numerical data were given as mean ± standard deviation (SD). Categorical data were given as percentages (%).

ROC curves were plotted to find the optimal threshold for PNI. The Youden index was calculated. The best threshold was 34.10, with a sensitivity and specificity of 0.70%. The median PNI value was 40.35, and the mean was 39.91. Patients were divided into "low PNI" and "high PNI" groups using this cut-off value. There were 43 patients in the low-PNI group and 115 in the high-PNI group. Each group was analyzed separately for age, comorbidities, BMI, and body surface area. All variables likely to show statistical significance in the univariate analysis were included.

Parametric values (e.g., weight loss and chemotherapy duration) between the two groups were compared using a t-test. The relationship between other categorical variables (e.g., degree of hematologic toxicity and pain) was assessed using the chi-square test. The calculated odds ratios were presented with 95% confidence intervals. A p-value of <0.05 was considered to indicate statistical significance.

Results

The demographic characteristics of the patients included in the study are shown in Table I. The average age of the patients was 52.1 years, the average body mass index (BMI) was 28.9 kg/m², and the average body surface area was 2.9 m².

With a sensitivity and specificity of 0.70, the optimal cut-off value for PNI was set at 34.10 (Figure 1). Based on this cut-off value, patients were divided into two groups: those with a low PNI value (≤34.10, n=43) and those with a high PNI value (>34.10, n=115). Separate analyses of age, comorbidities, BMI, and body surface area were performed between the groups, and no significant differences were observed (Table I). The mean age was 54.2 years in the low PNI group and 51.4 years in the high PNI group.

Based on the predefined cut-off value of 34.10, 43 patients (27.2%) were classified as low-PNI and 115 (72.8%) as high-PNI. Hematologic toxicity grades differed significantly between the two groups (Pearson $\chi^2(4)=12.36$, $p=0.015$). Examination of cell-wise adjusted residuals showed that this difference was primarily due to a markedly higher rate of

Table I: *Distribution of demographic characteristics of patients overall and by group*

	Low PNI(≤34.1) value group(n=43)	**High PNI(>34.1) value group(n=115)**	**Total patients (n=158)**	**p**
Age (year)	54.2	51.4	52.1	0.092
BMI (kg/m^2)	29.3	28.8	28.9	0.579
Average body surface area	1.6	3.5	2.9	0.475
Accompanying internal disease, n (%)				
None	%76.7	%78.9	%78.3	
Diabetes mellitus	%4.7	%5.3	%5.1	0.909
Hypertension	%18.6	%15.8	%16.6	0.282
Pre-operative CA125	1178.8	886.6	966.1	
Histological Type				
serous	%86	%72.2	%75.9	0.463
endometrioid	%7	%10.4	%9.5	
clear cell	%2.3	%7	%5.7	0.444
mixed type*	%0	%3.5	%2.5	
carcinosarcoma	%4.7	%5.2-	%5.1	
mucinous	%0	%1.7	%1.3	
Ascites				
None	%48.8	%55.7	%53.8	
Yes	%51.2	%44.3	%46.2	

Numerical variables with normal distribution were shown as mean ± standard deviation. Categorical variables are shown as numbers (%). p<0.05 indicates statistical significance.
**(For definitions, see: materials and methods) *mixed type (serous + endometrioid)*
PNI: Prognostic nutritional index, BMI: Body mass index, DM: Diabetes mellitus, HT: Hypertension

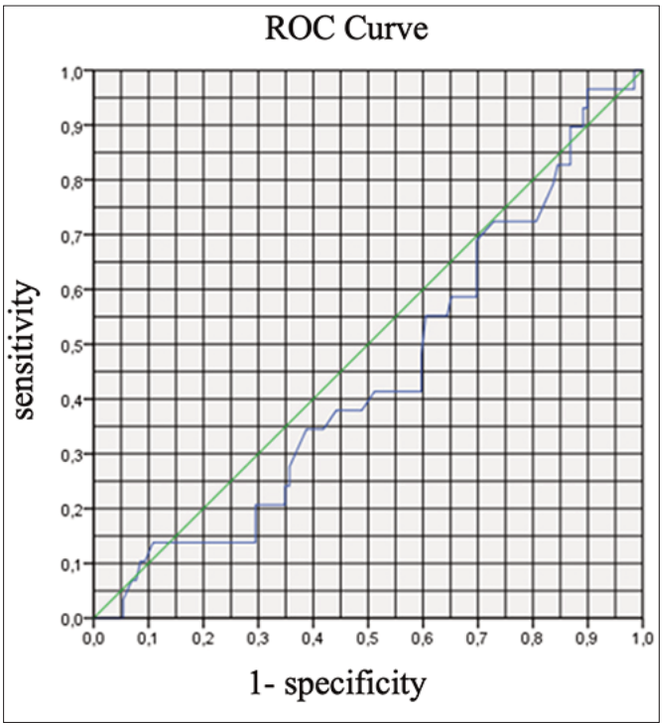

Figure 1: *ROC curve for calculating the PNI threshold for predicting hematologic toxicity*

grade 4 hematologic toxicity in the low-PNI group (37.2% vs. 15.7%; adjusted residual=2.9). In contrast, intermediate-grade toxicities (grades 2-3) were more frequently observed in the high-PNI group, resulting in a non-linear pattern across toxicity categories (Table II).

Given the ordinal nature of toxicity grading, an ordinal logistic regression model was constructed to evaluate whether the PNI group independently predicted a stepwise increase in hematologic toxicity. The model did not reach statistical significance (β=0.554, p=0.086) (Table III), indicating that although overall distributions differed between groups, the relationship did not follow a proportional, monotonic increase across toxicity levels. In summary, low pre-treatment PNI was specifically associated with a substantially higher likelihood of experiencing grade 4 hematologic toxicity, whereas the pattern across lower grades did not show a consistent ordinal trend. When toxicity grades were grouped into low (grades 0-2) and high (grades 3-4), no significant difference was observed between the groups (p>0.05) (Table IV).

Variables with p<0.20 in the univariate analyses (age, BMI, and PNI group) were included in an ordinal logistic regression model. After adjusting for age and BMI, PNI was not an independent predictor of higher-grade hematologic toxicity (β=0.473, OR=1.60, 95% CI: 0.85–3.04; p=0.146). Among all variables, age was the only statistically significant factor, with each one-year increase associated with a 3% increase in the odds of experiencing higher toxicity grades (β=0.031, OR=1.03, 95% CI: 1.00–1.06; p=0.048). BMI was not associated with toxicity severity (p=0.585). The proportional odds assumption was met (p=0.889), indicating an appropriate model fit (Table V).

Neurotoxicity, gastrointestinal pain, and alopecia were compared between the two groups, and no statistically significant differences were found in these toxicity parameters. During chemotherapy, weight loss was another parameter evaluated in both groups. The mean weight loss during treat-

Table II. *Distribution of hematologic toxicities in all grades according to PNI threshold*

Distribution of hematologic toxicity in all grades	Distribution of hematologic toxicity in all grades	Distribution of hematologic toxicity in all grades	Distribution of hematologic toxicity in all grades	Distribution of hematologic toxicity in all grades	Distribution of hematologic toxicity in all grades	Distribution of hematologic toxicity in all grades	Distribution of hematologic toxicity in all grades
		None	Grade 1	Grade 2	Grade 3	Grade 4	Total
Low PNI(≤34.1) value group(n=43)	Number of patients	4	8	5	10	16	43
Low PNI(≤34.1) value group(n=43)	Toxicity percentage	%9.3	%18.6	%11.6	%23.3	%37.2	%100
High PNI(>34.1) value group(n=115)	Number of patients	6	21	34	36	18	115
High PNI(>34.1) value group(n=115)	Toxicity percentage	%5.2	%18.3	%29.6	%31.3	%15.7	%100
p-value	p-value	0.015*	0.015*	0.015*	0.015*	0.015*	

PNI, prognostic nutritional index. p<0.05 indicates statistical significance.

Table III: *Ordinal logistic regression analysis of predictors of hematologic toxicity*

Predictor	**β (Estimate)**	**OR (Expβ)**	**95% CI**	**p**		
PNI ≤ 34.10	0.554	1.74	0.92- 3.27	0.086		
PNI > 34.10	Reference	-	-	-		
Statistics	**Statistics**	**Value**	**Value**	**p**		**χ^2**
Model fit (Final vs Intercept-only)	Model fit (Final vs Intercept-only)			*0.104*		2.641
				0.019	Pearson Goodness-of-fit	9.994
				0.022	Deviance Goodness-of-fit	9.662
				0.214	Test of Parallel Lines	1.545
				0.017	Nagelkerke R^2	2.641

PNI = Prognostic Nutritional Index. Low PNI was defined as ≤34.10 according to the ROC-based optimal cut-off. Hematologic toxicity was modeled as a five-level ordinal outcome (grades 0–4, CTCAE v4.0). Odds ratios (OR) were calculated as Exp(β), where β>0 and OR>1 indicate increased odds of transitioning to higher toxicity grades. The proportional odds assumption was met, confirming the ordinal logistic model's suitability. Statistical significance was set at p<0.05 (two-tailed)

Table IV: *Distribution of hematologic toxicities, classified into low and high grades according to PNI thresholds*

Hematologic toxicity	**Hematologic toxicity**	**Hematologic toxicity**	**Hematologic toxicity**	**Hematologic toxicity**
		Low-grade toxicities	High-grade toxicities	Total
Low PNI(≤34.1) value group(n=43)	Number of patients	7	26	43
Low PNI(≤34.1) value group(n=43)	Toxicity percentage	%39.5	%60.5	%100
High PNI(>34.1) value group(n=115)	Number of patients	61	54	115
High PNI(>34.1) value group(n=115)	Toxicity percentage	%53.0	%47.0	%100
p-value	p-value	0.091	0.091	

PNI, prognostic nutritional index.p<0.05 indicates statistical significance

Table 5. Multivariate Ordinal Logistic Regression Analysis for Predicting Hematologic Toxicity

Predictor	β (Estimate)	Std. error	OR (Expβ)	95% CI	p
Age (years)	0.031	0.016	1.03	1.00-1.06	***0.048****
BMI (kg/m²)	0.016	0.030	0.98	0.93-1.04	0.585
PNI ≤34.10 (Low)	0.473	0.325	1.60	0.85-3.04	0.146

Model χ^2=6.614, df=3, p=0.085, Nagelkerke R^2=0.043, Parallel lines test p=0.889 → model assumptions satisfied. PNI=Prognostic Nutritional Index; OR=Odds Ratio; CI=Confidence Interval. OR values calculated as Exp(β). Dependent variable: hematologic toxicity grade (0-4).Variables with p<0.20 in univariate analysis were entered into the multivariate model.

ment was 5.4 kg in the low PNI group and 2.35 kg in the high PNI group (p<0.05). Dose reductions during chemotherapy were more frequent in the low PNI group, about 2.66 times more frequent (p<0.05). The recurrence rate was also significantly higher in the low PNI group, about 1.61 times higher (p<0.05).

The use of G-CSF and ESP replacement, essential steps in toxicity management, was also recorded during patient follow-up. The low PNI group had a higher rate of G-CSF replacement (1.8 times more; p<0.05) and ESP replacement (1.8 times more; p<0.05).

The mean treatment completion time was 117.6 days in the low PNI group and 115.7 days in the high PNI group, with no statistically significant difference (p>0.05). Secondary hospitalizations due to deterioration of general condition, infections, or severe toxicity symptoms were not statistically different between the low and high PNI groups (p>0.05).

Discussion

Epithelial ovarian cancer (EOC) is predominantly diagnosed at an advanced stage, as it is largely asymptomatic in the early stages, which makes effective early intervention considerably more difficult and leads to a high mortality rate 1. The cornerstone of treatment for advanced EOC is cytoreductive surgery followed by platinum-based chemotherapy (2). However, the efficacy of this treatment is often compromised by the occurrence of chemotherapy-related toxicities, which can severely impact patient outcomes and quality of life (8).

This study focuses on the use of the Prognostic Nutritional Index (PNI) as a predictor of chemotherapy-related toxicities in patients with ovarian cancer. The PNI, which assesses both nutritional and inflammatory status, has shown promise in predicting outcomes and complications in various cancer types (4-6). In our analysis, we observed a significant correlation between lower pre-treatment PNI scores and higher rates of hematologic toxicity across all grades, reinforcing the usefulness of the PNI as a critical indicator of patient susceptibility to chemotherapy-related adverse effects (7,8). Moreover, the association between low PNI values and a higher incidence of severe toxicities requiring dose reductions and treatment modifications is particularly noteworthy (11,12). These findings are consistent with other studies suggesting that pre-treatment assessment of nutritional status and immunology may lead to more personalized treatment approaches that potentially improve therapeutic outcomes (13-15).

Interestingly, while our study confirms previous findings on the predictive value of PNI for hematologic toxicities, it also highlights non-significant differences in non-hematologic toxicities, such as neurotoxicity and alopecia, across PNI groups (6,16). This may suggest that while PNI is a robust predictor of hematologic adverse events, its predictive power for other types of toxicities may be limited. This suggests the need to develop more comprehensive predictive models that encompass a broader range of chemotherapy-related complications.

The implications of our study go beyond the mere prediction of toxicities. They emphasize the importance of integrating predictive tools such as PNI into clinical practice to preemptively identify patients at higher risk of severe toxicities. Such an approach not only optimizes patient management but also aligns with the broader goals of precision medicine, which aim to tailor treatment to individual patient characteristics (17-19).

This study has demonstrated the utility of PNI in predicting chemotherapy-related toxicities in patients with ovarian cancer, supported by robust statistical analyses and a ten-year retrospective observational dataset. However, the retrospective nature of the study limits causal conclusions, and the single-center design may affect the generalizability of the results. In addition, the study primarily examined hematologic toxicities; other significant toxicities may have been overlooked. Future research could extend these findings through prospective multi-center studies and include a broader spectrum of chemotherapy-related side effects to improve the clinical applicability of PNI in personalized medicine.

Conclusion

In summary, the PNI in this study is a valuable tool in the oncology armamentarium, providing a simple yet effective means of predicting chemotherapy challenges. Future research should aim to validate and refine the use of the PNI in larger, more diverse cohorts and to explore its integration with other prognostic tools to better guide treatment decisions in ovarian cancer and, potentially, other malignancies (20).

Declarations

Ethics approval and consent to participate: All participants provided written informed consent before enrollment in the study. The study was reviewed and approved by the Clinical Research Ethics Committee of the Republic of Turkey Ministry of Health Etlik Zubeyde Hanim Women's Diseases Training and Research Hospital (Ethics approval reference number: 2020/185, date 30.12.2020). All procedures were performed in accordance with the Declaration of Helsinki.

Availability of data and materials: The datasets and code used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflict of interest: The authors have no relevant financial or non-financial interests to disclose.

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Authors' contributions: ST: raised the presented idea. ST: NB: and ASD: Coteli designed the study. ST: and ASDC: developed the first draft of the manuscript. AA: AGE: analyzed and interpreted the data and drafted the manuscript. YU: participated in data analysis, interpretation, and draft revision. ST: AA: and AGE: participated in data collection and interpretation of results. YU: critically revised the manuscript. All authors contributed to the writing of the paper, and have read and approved the final manuscript.

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