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Assessing Pathological Complete Response in Locally Advanced Breast Cancer: The Role of Inflammatory and Nutritional Biomarkers

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ABSTRACT

Aim: Neoadjuvant chemotherapy (NAC) aims to achieve pathological complete response (pCR), which is linked to improved outcomes in locally advanced breast cancer (LABC). Identifying reliable predictors of pCR remains a clinical priority.

Methods: This retrospective study included 44 women, with a median age of 50 years, with stage 2B-3C breast cancer who underwent NAC followed by surgery. Inflammatory markers [systemic inflammation index (SII), neutrophil-to-lymphocyte ratio (NLR), platelet to lymphocyte ratio (PLR), erythrocyte-to-lymphocyte ratio (ELR), lymphocyte-to-C (LCR)] and nutritional indices [glucose-to-albumin ratio (GAR), hemoglobin-to-albumin ratio (HAR), prognostic nutritional index (PNI)] were analyzed. Receiver operating characteristic analysis determined optimal cut-off values, and binary logistic regression evaluated independent predictors of pCR.

Results: The overall pCR rate was 38.6%. Among histological subtypes, luminal B tumors were more frequent in both groups, with 40.7% in the non-pCR group and 29.4% in the pCR group. Triple-positive and HER2-positive tumors were more common in the pCR group. GAR ≤2.04 emerged as the only independent predictor of pCR (odds ratio=0.09, 95% confidence interval: 0.01-0.70, p=0.02). ELR >2.69 and LCR >0.64 showed significant associations with pCR (p=0.03 and p=0.04, respectively), though they lacked independent predictive value. SII, NLR, PLR, HAR, and PNI demonstrated no significant correlation with pCR.

Conclusion: This study assessed significant cut-off values, ELR >2.69 and LCR >0.64, that might predict the pCR in LABC. GAR, with a cut-off value of 2.04, was found to be an independent predictive marker for pCR.

Keywords: Breast cancer, inflammatory marker, neoadjuvant chemotherapy, nutritional marker, pathological complete response

Introduction

Breast cancer is the most frequently diagnosed cancer in women and the leading cause of death in women [1]. Breast cancer is divided into various subtypes according to the receptor status [2]. These subtypes play a crucial role in treatment decisions, as several studies have shown that achieving pathological complete response (pCR) after neoadjuvant treatment significantly improves breast cancer prognosis [3,4].

A meta-analysis demonstrated that pCR was associated with prolonged survival [5]. Recently, Huang et al. [6] confirmed the strong association between pCR and long-term survival outcomes, especially in triple-negative breast cancer (TNBC) patients.

Since achieving pCR has become a target in patients receiving neoadjuvant treatment, recent studies have focused on predicting the neoadjuvant chemotherapy (NAC) response [7]. Tools are inflammatory markers such as systemic inflammation index (SII), tumor-infiltrating lymphocytes, neutrophil to lymphocyte ratio (NLR), and platelet to lymphocyte ratio (PLR). They effectively predicted treatment response in TNBC, with NLR standing out as an independent predictor [8]. Another

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study showed that while markers such as NLR, white cell count, and lymphocyte count could help predict pCR, their use in specific breast cancer subtypes remains uncertain due to the lack of standardized cut-off values, highlighting the need for further research [9]. In a meta-analysis, high PLR was associated with poor prognosis, lymph node metastasis, advanced tumor node metastasis (TNM) stage, and distant metastasis in breast cancer patients [10]. High NLR has been consistently associated with poorer survival outcomes in breast cancer patients. Its prognostic significance remains robust across various clinicopathological parameters, including disease stage and molecular subtypes [11].

Other markers have also been studied in various studies. Hu et al. [12] demonstrated that a low preoperative hemoglobin-to-albumin ratio (HAR) is an independent risk factor for poor short-term survival in gastric cancer patients. Low values of the lymphocyte to C-reactive protein (CRP) ratio (LCR) indicated poor prognosis in early-stage breast cancer [13]. Additionally, nutritional indexes, such as the prognostic nutritional index (PNI), might predict the treatment response in cancer patients. The PNI has been reported to have a stronger prognostic value than inflammatory markers [14].

The pCR is a well-known endpoint for neoadjuvant treatment in breast cancer. Additionally, predicting responses has become popular with usable tools in daily applications. Hence, we aimed to evaluate the predictive role of inflammatory markers and nutritional indexes in predicting the response to NAC to better understand which patients will achieve the best outcome from chemotherapy.

Methods

From 2023 to 2024, a total of 44 women evaluated by a multidisciplinary tumor board opted to undergo NAC treatment prior to curative surgery and were subsequently included in the study. Pathological diagnosis was established through needle biopsy, and surgical specimens. The study used the eighth edition of the American Joint Committee on Cancer's TNM staging system. It included patients with locally advanced breast cancer (LABC), specifically those with stage 2B disease (T3N0) and those with stage 3A to 3C disease, AJCC [15]. After the completion of NAC, all patients underwent breast-conserving surgery (BCS) or modified radical mastectomy (MRM) and axillary lymph node dissection (ALND) or sentinel lymph node biopsy.

Patients' data regarding age, laboratory parameters, pathological reports, and chemotherapy regimens were retrospectively obtained from their charts. Patients did not sign the informed consent form, were under 18 years old, had oligometastatic disease, could not complete the NAC, and had eastern cooperative oncology group performance status 2, 3, and 4 were excluded from the data analysis.

A written informed consent form was obtained from each patient at the time of admission to our clinic. The Local Ethics Committee of University of Health Sciences Türkiye, Kanuni Sultan Süleyman Training and Research Hospital approved the study (decision no: KAEK/2024.01.5, date: 05.01.2024).

The markers evaluated in this study were defined as follows:

1. SII: This was calculated by multiplying the platelet count by the neutrophil count and then dividing by the lymphocyte count.

2. NLR: This was determined by dividing the neutrophil count by the lymphocyte count.

3. PLR: This was determined by dividing the platelet count by the lymphocyte count.

4. Glucose-to-albumin ratio (GAR): This was calculated by dividing serum glucose levels by serum albumin levels.

5. Erythrocyte-to-lymphocyte ratio (ELR): This was obtained by dividing the erythrocyte count by the lymphocyte count.

6. HAR: This was calculated by dividing hemoglobin levels by albumin levels.

7. LCR: This was calculated by dividing the lymphocyte count by the CRP level.

8. PNI: This was derived using the formula: 10×serum albumin (in g/dL)+0.005×total lymphocyte count (per mm^3).

Pathological Assessment

Histopathological classification was carried out using immunohistochemistry (IHC). The luminal subtype was identified as human epidermal growth factor receptor (HER)2-negative and estrogen receptor (ER)-positive. This group was further divided into luminal A, characterized by low Ki-67 (<20%), and luminal B, characterized by high Ki-67 (≥20%). HER2 positivity was indicated by IHC 3+or silver in situ hybridization positivity. The triple-negative (TN) subtype was defined by the absence of ER, progesterone receptor (PR), and HER2 expression. The pCR was defined as a complete absence of residual invasive cancer in the breast tissue.

Neoadjuvant Chemotherapy Regimens

Patients in the luminal group were administered four cycles of either epirubicin (75 mg/m^2) or adriamycin (60 mg/m^2) combined with cyclophosphamide (600 mg/m^2) [adriamycin (doxorubicin)+cyclophosphamide/epirubicin+cyclophosphamide (AC/EC)] every three weeks. This was followed by 12 weekly cycles of paclitaxel (80 mg/m^2). For those with HER2-positive tumors, the treatment included AC/EC followed by paclitaxel in conjunction with dual HER2 blockade: trastuzumab (initial dose of 8 mg/kg, then 6 mg/kg, administered every three weeks) and pertuzumab (initial dose of 840 mg, then 420 mg, administered every three weeks). TNBC patients received a dose-dense regimen consisting of four cycles of AC/EC followed by 12 weekly cycles of paclitaxel, with those having BRCA mutations also undergoing 12 cycles of carboplatin [2 area under the curve (AUC)].

Statistical Analysis

Statistical analyses were conducted using Statistical Package for the Social Sciences (SPSS) version 22.0 (SPSS Inc., Chicago, IL, USA). Data evaluation incorporated descriptive statistics, such as mean, standard deviation, median, frequency, ratio, minimum, and maximum values, and the Shapiro-Wilk test to

assess the normality of data distribution. Pearson correlation coefficients were used for variables with normal distribution, whereas Spearman rank correlation was applied for non-normally distributed variables. The Student's t-test was employed to compare quantitative data between two groups with normal distribution, while the Mann-Whitney U test was used for non-normally distributed groups. A receiver operating characteristic (ROC) analysis was conducted to determine the optimal cutoff values of inflammatory markers for predicting a pCR. The relationship between survival time and each independent variable was quantified using 95% confidence intervals (CI). All statistical tests were two-tailed, with p≤0.05 deemed statistically significant.

Results

Forty-four women, with a median age of 50 (range: 30-72), were included in this study. Twenty-six were premenopausal, while 18 were postmenopausal. At baseline, radiological assessment showed T1 disease in 14 women, T2 in 26, T3 in 3, and T4 in 1. Meanwhile, ten, seven, twenty-four, and 3 women had radiologically assessed N0, N1, N2, and N3 disease, respectively.

All tumors exhibited invasive ductal carcinoma histology. The molecular subtypes of the patients were categorized as follows: nine patients were classified in the luminal A group, 16 patients were in the luminal B HER2-negative group, 10 patients in the luminal B HER2-positive group, three patients in the HER2-positive ER-negative group, and six patients were classified in the TN group.

Thirty-three had undergone BCS (i.e., lumpectomy or partial mastectomy), and the remaining patients had undergone modified or subcutaneous mastectomy. Despite 27 women having N2 or N3 disease at the baseline, only 9 of them underwent ALND. Histopathological analysis of surgical specimens after NAC revealed pCR in 17 cases (38.6%).

Table 1 summarizes the patient's characteristics.

The Mann-Whitney U test demonstrated a significant association between pCR and LCR (p=0.04), GAR (p=0.006), and ELR (p=0.03) (Table 2). However, there was no association between pCR and SII, NLR, PLR, HAR and PNI (all >0.05).

ROC analysis was performed to determine cut-off values, which identified thresholds of 2.69 for ELR (p=0.02, AUC: 0.70, 95% CI: 0.56-0.91), 0.64 for LCR (p=0.04, AUC: 0.71, 95% CI: 0.51-0.91), 102.8 for prognostic index (PI) (p=0.03, AUC: 0.26, 95% CI: 0.08-0.45), and 2.04 for GAR (p=0.006, AUC: 0.20, 95% CI: 0.04-0.37), respectively (Figure 1). The sensitivity and specificity were 53.8% and 62.1% for LCR, 61.5% and 12.1% for PI, 53.8% and 72.2% for ELR, 61.5% and 12.1% for GAR, respectively (Figure 1).

Table 1. The patients and tumor characteristics according to the pCR status

Characteristics	pCR n (%)	Non-pCR n (%)	p
Total patients	17 (38.6%)	27 (61.4%)	-
Menopausal status			
Premenopause	11 (64.7%)	15 (55.6%)	0.6
Postmenopause	6 (35.3%)	12 (44.4%)	
Initial T status			
T1	7 (41.2%)	7 (25.9%)	0.6
T2	9 (52.9%)	17 (63%)	
T3	1 (5.9%)	2 (7.4%)	
T4	0	1 (3.7%)	
Initial nodal status			
N0	6 (35.3%)	4 (14.8%)	0.03
N1	0	7 (25.9%)	
N2	11 (64.7%)	13 (48.1%)	
N3	0	3 (11.1%)	
Histologic type			
Luminal A	2 (11.8%)	7 (25.9%)	0.5
Luminal B	5 (29.4%)	11 (40.7%)	
HR positive HER-2 positive	5 (29.4%)	5 (18.5%)	
HR negative HER-2 positive	2 (17.6%)	1 (3.7%)	
TNBC	3 (17.6%)	3 (11.1%)	
ELR			
≤2.69	3 (21.43%)	11 (78.57%)	0.03
>2.69	10 (58.82%)	7 (41.18%)	
LCR			
≤0.64	4 (26.67%)	11 (73.33%)	0.09
>0.64	9 (56.25%)	7 (43.75%)	
GAR			
≤2.04	7 (77.78%)	2 (22.22%)	0.01
>2.04	6 (27.27%)	16 (72.73%)	

HR: Hormone receptor, TNBC: Triple negative breast cancer, ELR: Erythrocyte lymphocyte ratio, LCR: Lymphocyte C-reactive protein ratio, GAR: Glucose-to-albumin ratio, pCR: Pathological complete response

Table 2. The mean values of systemic inflammatory markers

Marker	pCR mean±SD	Non-pCR mean±SD	Mann-Whitney U test p
ELR	2.9±1.0	2.9±0.8	<0.05
NLR	2.8±1.2	2.8±1.0	≥0.05
PLR	158.2±59.7	158.2±61.5	≥0.05
LCR	1.8±1.7	1.8±6.4	<0.05
HAR	0.3±0.03	0.3±0.02	≥0.05
PNI	485.6±32.0	485.6±30.8	≥0.05
SII	712.5±310.4	758.1±347.7	>0.05
GAR	2.0±0.3	2.6±1.0	<0.05

ELR: Erythrocyte lymphocyte ratio, NLR: Neutrophil lymphocyte ratio, PLR: Platelet lymphocyte ratio, LCR: Lymphocyte C-reactive protein ratio, HAR: Hemoglobin albumin ratio, PNI: Prognostic nutritional index, SII: Sytemic immune inflammation index, GAR: Glucose-to-albumin ratio, pCR: Pathological complete response, SD: Standard deviation

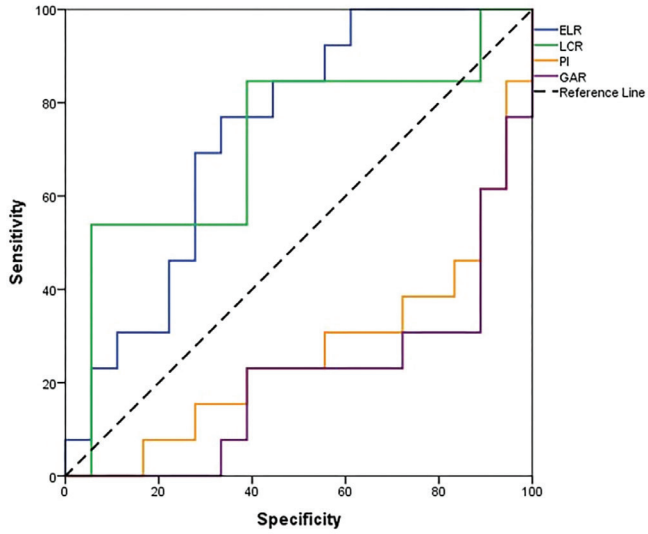

Figure 1. The ROC curve for inflammatory and nutritional markers predicting pCR
ROC: Receiver operating characteristic, pCR: Pathological complete response, ELR: erythrocyte-to-lymphocyte ratio, LCR: Lymphocyte-to-C-reactive protein ratio, GAR: Glasgow albumin ratio, PI: Prognostic index

In comparing the pCR and non-pCR groups, no significant differences were observed across histological subtypes and menopausal status. Among histological subtypes, luminal B tumors were more frequent in both groups, with 40.7% in the non-pCR group and 29.4% in the pCR group. Triple-positive and only HER2+tumors were more prevalent in the pCR group. For inflammatory markers, patients with a low GAR (≤2.04) showed a significantly higher proportion of pCR (53.8%) compared to the non-pCR group (p=0.01) (Figure 2). Similarly, patients with an ELR >2.6 had a significantly higher rate of pCR (76.9%) compared to those below this threshold (p=0.03) (Figure 3). Although a trend toward higher pCR rates was observed among patients with an LCR above 0.64, this did not reach statistical significance (Table 2).

The binary logistic regression analysis indicated that GAR was the only significant predictor of pCR, with a coefficient (β) of -2.3 and an odds ratio (OR) of 0.09 (p=0.02, 95% CI: 0.01-0.70). Lower GAR values were associated with a significantly higher likelihood of achieving pCR, with a 91% increase in the odds of pCR for each unit decrease in GAR. The other markers, including ELR, LCR, and PI, did not reach statistical significance, with ORs of 2.3 (95% CI: 0.38-14.76), 1.5 (95% CI: 0.26-9.31), and 0.3 (95% CI: 0.03-2.83), respectively (Table 3).

Discussion

Predicting the response to NAC in breast cancer reduces exposure to ineffective treatments, protects against side effects, and improves patients' quality of life [16]. Accurate prediction of response improves overall survival (OS) by enabling the creation of personalized treatment plans [17]. Furthermore, achieving pCR is directly related to long-term survival and allows us to determine appropriate treatment strategies [18].

A meta-analysis by Haque et al. [5] reported that 19% of 13,939 women achieved pCR after neoadjuvant treatment. According to subgroups, the pCR rate was lowest in the luminal A subtype at 0.3% and highest in the HER2-positive subtype at 38.7%.

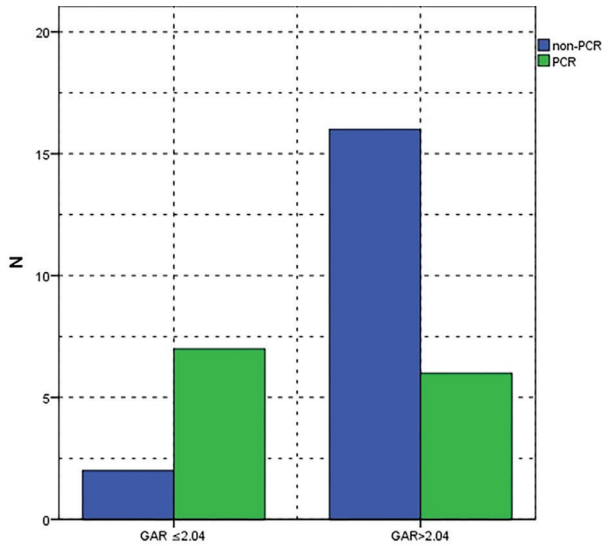

Figure 2. The number of patients in the pCR and non-pCR groups in terms of GAR value
pCR: Pathological complete response, GAR: Glasgow albumin ratio

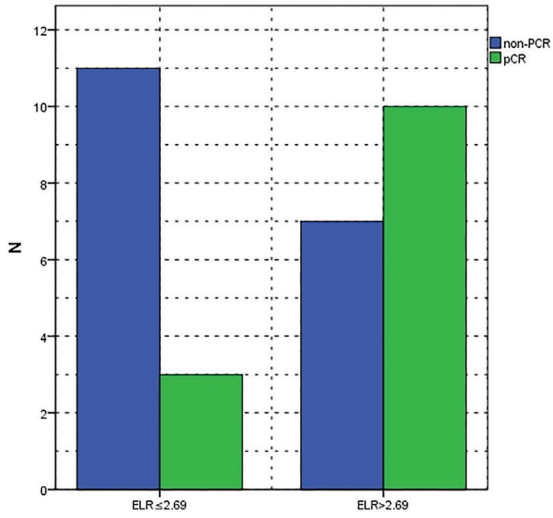

Figure 3. The number of patients in the pCR and non-pCR groups in terms of ELR value
pCR: Pathological complete response, ELR: Eosinophil-to-lymphocyte ratio

Table 3. The binary logistic regression analysis for the pCR predictivity of inflammatory and nutritional markers

Factors < vs ≥	Coefficient β	Wald x^2	p	OR	95% CI
ELR	0.86	0.86	0.3	2.3	0.38-14.76
LCR	0.45	0.24	0.6	1.5	0.26-9.31
GAR	-2.3	5.29	0.02	0.09	0.01-0.70

ELR: Erythrocyte lymphocyte ratio, LCR: Lymphocyte C-reactive protein ratio, GAR: Glucose-to-albumin ratio, pCR: Pathological complete response, OR: Odds ratio, CI: Confidence interval

Antonini et al. [19] showed that the overall pCR rate was 22.7%, and higher pCR rates were reported in TN and luminal B subtypes. In addition, HR status was predictive of pCR rates, and ER-/PR +phenotype showed increased pCR rates due to its sensitivity to chemotherapy [20]. Our study's overall PCR rate was 38.6%, which was higher than the rate reported in the literature. The reason might be the inclusion of a higher rate (36%) of HER2-positive or TNBC patients. On the other hand, the small sample size might also cause bias.

Another aim of neoadjuvant treatment is to omit the ALND and to reduce the mastectomy rates [21]. Goktas Aydin et al. [22] reported that 51.6% and 43.1% of patients underwent BCS and SNLB, respectively. In our study, we demonstrated the efficacy of neoadjuvant treatment on surgical outcomes by showing that only five patients (11.3%) underwent MRM and six patients (13.6%) underwent ALND.

In terms of inflammatorymarkers; ELR hasn't been studied well in breast cancer however Wang et al. [23] found it was a significant predictor for axillary lymph node metastasis which was also linked with the survival. We evaluated the predictive significance of the ELR and identified a significant cutoff value of 2.69 (p=0.02, AUC: 0.70, 95% CI: 0.56-0.91). Among patients who achieved pCR, 3 (21.4%) had an ELR ≤2.69, compared to 11 (78.6%) in the non-pCR group. These findings suggest that a lower ELR (≤2.69) may be associated with a reduced likelihood of achieving pCR, highlighting its potential role as a predictive marker in this setting.

A study, examining 299 breast cancer patients undergoing NAC suggested that patients with a higher baseline LCR (cut-off: 1.9) tended to respond better to treatment. Those who achieved a pCR had slightly lower LCR levels at diagnosis (p=0.049) [24]. In contrast, our findings demonstrated a lower LCR cut-off value of 0.64 (p=0.04, AUC: 0.71, 95% CI: 0.51-0.91) associated with pCR, though logistic regression analysis did not confirm it as an independent predictor for neoadjuvant treatment response. A few studies have examined LCR that might explain the discrepancy, with most focusing on CRP for prediction and prognosis. These retrospective studies included diverse breast cancer subtypes, limiting generalizability.

The predictive and prognostic role of SII, NLR, and PLR has been extensively researched. Yang et al. [25] revealed that SII, NLR, and PLR with a cut-off value of 0.827, 0.827, and 0.810, respectively, indicated a higher predictive value for response to NAC. A meta-analysis confirmed these results by showing a significant association between high SII and poor OS in breast cancer patients [26]. A recent study also reported lower SII (OR=0.596; 95% CI: 0.429-0.827; p=0.002) and higher NLR (OR=1.320; 95% CI: 1.016-1.716; p=0.038), and PLR (OR=1.474; 95% CI: 1.058-2.052; p=0.022) were significantly associated with a higher likelihood of achieving pCR [27]. In contrast to these positive findings, Garcia-Torralba et al. [28], concluded that NLR lacked prognostic utility in early breast cancer, showing no significant association with survival across different tumor subtypes. Also, Ji and Wang [26] reported limited prognostic utility for NLR and PLR in breast cancer patients.

However, our results did not show a significant association between SII, NLR, or PLR and pCR rates, which challenges their predictive value in this cohort. This lack of correlation may be attributed to several factors, including the relatively small sample size, heterogeneity of molecular subtypes, or baseline disease burden variations.

Pan et al. [29] reported that GAR may be a clinically significant risk factor in breast cancer. A meta-analysis showed that low GAR was significantly associated with shorter OS and higher lymph node metastasis rates in cancer patients [30]. Similarly, our study identified GAR as the only independent predictor of pCR in binary logistic regression analysis, with a cut-off value of 2.04. Patients with GAR ≤2.04 had a significantly higher pCR rate (53.8%), and each unit decrease in GAR increased the odds of achieving pCR by 91%. Clinically, GAR could function as an early stratification tool: patients with high GAR values may benefit from more intensive monitoring, alternative therapeutic strategies, or additional nutritional and metabolic interventions to enhance chemosensitivity. Incorporating GAR into pre-treatment evaluation may thus enable more tailored neoadjuvant approaches, reducing overtreatment and improving therapeutic outcomes.

Higher PNI values have been associated with increased pCR rates and survival in trials [31,32]. Although Qu et al. [31] demonstrated that patients with a high PNI (≥53) had a significantly increased pCR rate (OR=2.217, 95% CI: 1.215-4.043, p=0.009), our study couldn't determine any correlation with the pCR.

HAR, another nutritional marker, is an orphan marker that hasn't been studied in cancer patients. Lower HAR values were significantly linked with poor survival in gastric cancer patients [12]. The hemoglobin, albumin, lymphocyte, and platelet (HALP) score was studied in early-stage breast cancer patients, showing that higher HALP scores independently predicted prognosis in both OS and progression-free survival [33]. Contrary to this, we could not demonstrate any significance between treatment responses and HAR. The discrepancy might be explained by the absence of survival outcomes in our study. We only assessed the PCR rates, which are believed to be closely linked to survival.

Study Limitations

This study's primary limitation is the small sample size, which may restrict the statistical power needed to establish significant associations. The absence of long-term survival data further limits the ability to evaluate the prognostic value of the studied markers. Additionally, heterogeneity in molecular subtypes may introduce variability in response rates. However, our study contributes to the evolving understanding of inflammatory and nutritional markers in predicting NAC response in LABC. By identifying GAR as an independent predictor and proposing novel cut-off values for ELR, LCR, and PI, this research offers potential clinical guidance for stratifying patients likely to achieve pCR. These insights and existing literature may support personalized treatment planning and improve outcomes.

Conclusion

Our findings highlight GAR's capability as a robust, standalone predictor of pCR in LABC. Additionally, ELR and LCR may offer valuable insights for creating personalized treatment strategies and improving predictions for NAC response. However, due to this study's limited sample size and retrospective nature, these results should be viewed carefully. Future research involving larger, multicenter cohorts or prospective designs is highly recommended to confirm the predictive value of GAR and other identified biomarkers.

Ethics

Ethics Committee Approval: The Local Ethics Committee of University of Health Sciences Türkiye, Kanuni Sultan Süleyman Training and Research Hospital approved the study (decision no: KAEK/2024.01.5, date: 05.01.2024).

Informed Consent: A written informed consent form was obtained from each patient at the time of admission to our clinic.

Footnotes

Authorship Contributions

Concept: S.G.A., S.D., Design: S.G.A., Data Collection or Processing: E.N.D., E.K.Y., T.E., S.D., Z.B.Y.İ., M.U., F.B.A., O.T., Analysis or Interpretation: S.G.A., T.E., S.D., Literature Search: E.N.D., E.K.Y., S.G.A., Writing: E.N.D., E.K.Y., S.G.A.

Conflict of Interest: No conflict of interest was declared by the authors.

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