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Is the albumin/globulin ratio a predictor of response to neoadjuvant chemotherapy before cystectomy for muscle-invasive bladder cancer?

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Introduction The objective of this study is to ascertain whether the albumin-to-globulin ratio (AGR) can predict the response to neoadjuvant chemotherapy (NAC) in patients with muscle-invasive bladder cancer and pure urothelial carcinoma histology who have undergone NAC prior to cystectomy.

Material and methods The study population comprised patients who underwent diagnostic biopsy with complete transurethral resection of a bladder tumor in our hospital, and for whom the pathology result was muscle-invasive pure urothelial cell carcinoma (pT2), and who received a minimum of three courses of cisplatin-based NAC. Patients were divided into two groups, responders and non-responders, according to their chemotherapy response.

Results A response was observed in 81 (54%) patients. The most significant difference between the two groups was found in the AGR scores. The median AGR was 1.7 (1.1–3.2) in the responders and 1.4 (0.7–2.4) in the non-responders (p = 0.001). Using ROC analysis, the optimal cut-off value of AGR for predicting chemotherapy response was determined to be 1.61. Multivariate analysis demonstrated that elevated AGR values (>1.61) exhibited a more substantial impact on response in comparison to other parameters. When the parameters that had a significant effect on survival were investigated with Cox regression analysis, a high AGR with chemotherapy response was found to have more significant effect on survival.

Conclusions We think that, in conjunction with established clinicopathological factors, AGR can be utilized for the selection of patients for NAC.

Key Words: albumin-to-globulin ratio ‹› muscle-invasive bladder cancer ‹› neoadjuvant chemotherapy

INTRODUCTION

The standard treatment for patients with urothelial muscle invasive bladder cancer (MIBC) is radical cystectomy (RC) [1]. However, recurrence and distant metastasis occur in 20–30% of patients who undergo surgery alone, which has a significant impact on their quality of life [2]. The utilization of neoadjuvant chemotherapy (NAC) has been a longstanding practice, with the objective of enhancing outcomes and extending overall survival (OS) [3]. The extra life expectancy from using NAC is only 5%, because not all patients respond to NAC, and this is the main problem with using NAC [4]. In cases that are resistant to NAC agents, the administration of delayed RC may have a deleterious effect on survival [4]. Furthermore, the administration of NAC in cases of refractory disease carries a significant risk of overtreatment. The selection of patients for NAC is therefore of paramount

importance, but there is a paucity of predictive markers of response to chemotherapy [5, 6]. Several studies have correlated the pre-NAC blood-based neutrophil-to-lymphocyte ratio (NLR) with response to NAC and oncological outcomes. Promising results have been obtained for NLR as a prognostic marker in this patient group [3–6].

Serum albumin and globulins represent the two primary serum proteins, and they can be utilized as indicators of this inflammatory process. During the process of inflammation, serum albumin levels decrease, while globulin levels increase [7, 8]. The link between inflammation and the development and progression of cancer is widely accepted and has been demonstrated in bladder cancer [9]. In recent years, there has been an increasing focus on the potential of inflammatory parameters as a means to predict cancer outcomes. Consequently, there has been an increase in systemic inflammatory biomarker studies in recent years, because they are low cost and can aid in the understanding of the impact on prognosis.

The albumin-to-globulin ratio (AGR) is a measure that combines the two indexes (albumin and globulin). Several recent studies have investigated the role of AGR as an independent prognostic factor for urological cancers, including prostate, kidney, and bladder cancer [10–14]. The extant literature demonstrates that patients diagnosed with bladder cancer who exhibit low AGR levels tend to demonstrate a poorer prognosis. However, the effect of AGR in predicting NAC response has not yet been reported in the literature.

The objective of this study is to ascertain whether AGR can predict the response to NAC in patients with MIBC and pure urothelial carcinoma histology who have undergone NAC prior to cystectomy.

MATERIAL AND METHODS

Data collection and patients

Following approval from the institutional review board, this retrospective study identified a cohort of patients who had undergone RC at our institution, and subsequently evaluated those who had been treated with NAC prior to RC. Written informed consent was obtained from all living participants. The data regarding demographics, clinicopathological features and outcomes was collected retrospectively from the medical records of our hospital. The study population comprised patients who underwent diagnostic biopsy with complete transurethral resection of bladder tumor (TUR-BT) in our hospital, and for whom the pathology result was muscle-invasive pure urothelial cell carcinoma (pT2), and who received a minimum of three courses of cisplatin-based NAC. All macroscopically visible tumors were completely resected during TUR-BT, and all patients were staged as cT2 (cT2-T4a, N0-2, M0) at the time of initial diagnosis. Routine blood tests were performed within 30 days prior to NAC. The blood tests undertaken included albumin, globulin, and total protein, in addition to standard parameters. The AGR was calculated using this formula: albumin/(total protein-albumin). The following data were obtained and recorded from patient files: baseline clinicopathological characteristics, clinical T stage and lymph node status (N) based on preoperative imaging, presence of hydronephrosis, prognostic factors such as the presence of lymphovascular invasion (LVI) and carcinoma *in situ* (CIS) on TUR BT pathology, response to chemotherapy, and clinical follow-up. All patients underwent preoperative magnetic resonance imaging (MRI), and Vesical Imaging–Reporting and Data System (VI-RADS) scores were determined (data are not shown). Patients with active autoimmune disease, chronic inflammatory disease or hematological disease, and a history of concomitant secondary cancer were excluded from the study. Furthermore, patients exhibiting variant histology were excluded due to an inadequate number of patients meeting the inclusion criteria. Additionally, patients who received NAC but not RC were excluded from the study, as it was not possible to evaluate their pathological response to NAC. The choice of urinary diversion was at the surgeon's discretion. Both TUR-BT and cystectomy pathologies were assessed by the same uropathologist.

A total of 150 patients who met the specified criteria were included in the study. The 5-year follow-up of 120 of these patients was completed. Patients were divided into two groups, responders and non-responders, according to their chemotherapy response. The pathological response (PR) was defined as the reduction of RC to a lower pathological stage after NAC. The pathological complete response (pCR) was designated as T0, whilst the incomplete response (IR) was categorized as Ta-T1.

The primary endpoint of the study was to determine the AGR cut-off associated with achieving a response in RC after NAC, and the secondary endpoint was to determine OS by AGR cut-off in patients completing five years of follow-up.

Follow-up

All patients were followed every 3 months for the first 2 years after surgery and every 6 months

thereafter. The follow-up process entailed a physical examination, a comprehensive blood chemistry analysis, and a thorough functional evaluation. Chest radiography and abdominal ultrasonography were conducted on a six-month basis. The initial follow-up abdominal computed tomography examination was conducted three months after surgery, with subsequent annual follow-ups performed.

Statistical analysis

The analyzes were made via IBM SPSS statistics 27.0. To examine numeric variables' normality, we used the Kolmonorov-Smirnov test. The numerical variables with a normal distribution were expressed as mean ±standard deviation. Data without a normal distribution were presented as median (min-max). Categorical variables were presented as number and percentage. The statistical analysis was conducted using a variety of methods, including the T-test, Mann-Whitney U-test, and chi-squared test, depending on the nature of the variable in question. Receiver operating characteristic curve (ROC) analysis was employed to ascertain the optimal cut-off value of AGR in predicting NAC response. A logistic regression model was used to identify predictors of pathological response to NAC. In 120 patients with 5-year follow-up, the effect of parameters on OS was investigated by Kaplan-Meier test. The log-rank method was employed to ascertain statistical significance. Parameters with statistically significant effects on survival were evaluated using Cox regression modelling.
p-values <0.05 were considered statistically significant.

Bioethical standards

The study was compatible with the Helsinki Declaration for laws and regulations, good clinical practice, and ethical principles and was approved by the Ethics Committee (28.01.2025) of Prof. Dr. Cemil Tascioglu City Hospital in Istanbul (2025-41).

RESULTS

Association with clinical and pathologic features

The clinicopathological characteristics of the 150 patients included in the study are given in Table 1. The median follow-up period was 45 months for all patients included in the study, and 58 (38.7%) patients died. A response was observed in 81 (54%) patients, including 32 cases of pCR and 49 instances of IR (Figure 1). The mean age of the responding patients was 67.5 ±7.5 years, and there was no significant difference in age between the responding and non-responding groups (p = 0.125) (Table 1). The most significant difference between the two groups was found in the AGR scores. The median AGR was 1.7 (1.1–3.2) in the responders and 1.4 (0.7–2.4) in the non-responders (p = 0.01).

Identification of the optimal cut-off value for albumin-to-globulin ratio

Using ROC analysis, the optimal cut-off value of AGR for predicting chemotherapy response was determined to be 1.61. The area under the curve (AUC) was found to be 0.814 (95% CI: 0.788–0.917), and the curve was determined to be statistically significant (p = 0.01) (Figure 2). According to the 1.61 cut-off point, the sensitivity and specificity of AGR in predicting response were found to be 74.1% and 91.3%, respectively (Figure 2). While 60 (90.9%) patients with a high AGR (>1.61) had a response,

Table 1. *Characteristic features of patients*

Variable	Response		p
	Responder (n = 81)	Non-Responder (n = 69)	
Age [years]	67.5 ±7.5	65.6 ±7.8	0.125[a]
Albumin [g/l]	38.2 ±6.8	36 ±6.4	0.045[a]*
Globulin [g/l]	21.6 ±4.5	26.7 ±5.4	0.001[a]*
Total protein [g/l]	59.8 ±9.7	62.8 ±9.5	0.065[a]
Tumor size [cm]	4 (3–6)	4 (3–6)	0.47[b]
AGR	1.7 (1.1–3.2)	1.4 (0.7–2.4)	0.001[b]*

[a]t test
[b]Mann-Whitney U test
*Significant
AGR – albumin-to-globulin ratio

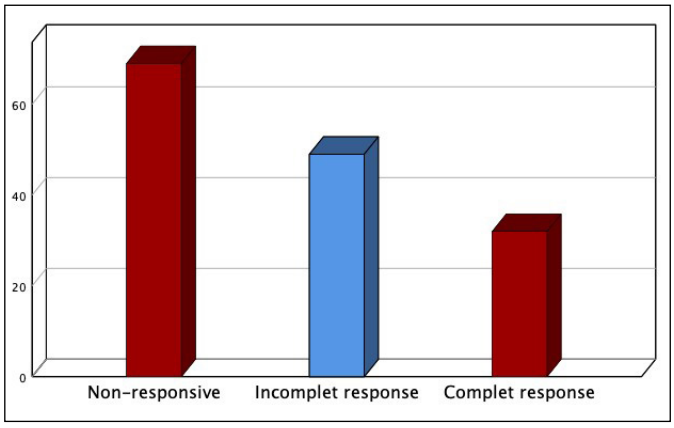


Figure 1. *Distribution of chemotherapy response.*

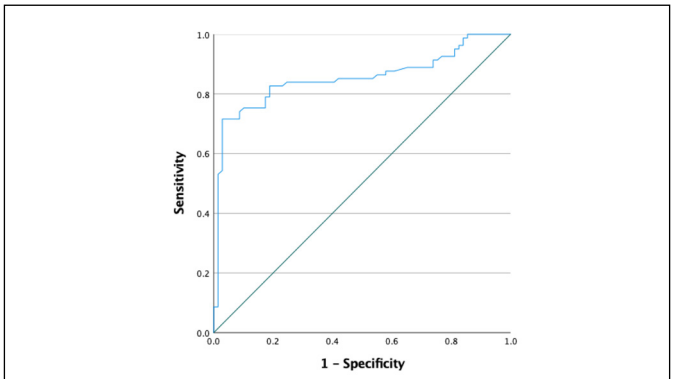
63 (75%) patients with a low AGR (<1.61) had no response. According to these results, the positive predictive value (PPV) and negative predictive value (NPV) of AGR for predicting chemotherapy response were found 90.9% and 75%, respectively (Figure 2, Table 2).

Multivariate analysis

To investigate the effect on chemotherapy response of the parameters high AGR, presence of LVI, smoking habits, and lymph node status, which showed a statistically significant difference between groups, multivariate regression analysis was employed. The findings of the study revealed that non-smoking status and the absence of LVI in conjunction with high AGR (>1.61), were all effective in predicting response when utilized in multivariate analyses. However, multivariate analysis demonstrated that elevated AGR values (>1.61) exhibited a more substantial impact on response in comparison to other parameters (p = 0.001, OR = 23.024 CI 8.148–65.062) (Table 3).

Association with overall survival

The following were linked to better overall survival: chemotherapy response (Figure 3A), absence of CIS (Figure 3B), absence of LVI (Figure 3C), no smoker (Figure 3D), a high AGR (>1.6) (Figure 3E), and a low clinical T stage (Figure 3F, Table 4). When the parameters that had a significant effect on survival according to Kaplan-Meier and Log-Rank tests were investigated with Cox regression analysis, a high AGR with chemotherapy response was found to have more significant effect on survival (Table 5).



Area	P	95% C.I.		Sensitiviy	Specifity	PPV	NPV	Cut Off
		Lower	Upper					
0.814	0.001	0.788	0.917	74.1%	91.3%	90.9%	75%	1,61

Figure 2. *Determination of cut-off value with ROC analysis.*

Additional analyses

Further analyses were conducted to determine whether the observed correlation between AGR and NAC response was merely a consequence of low ALB concentrations. It was found that hypoalbuminemia (<35 g/l) alone had no effect on chemotherapy response and OS (Tables 2 and 4).

Table 2. *Parameters that affect progression*

Variable		Response		p
		Responder n (%)	Non-responder n (%)	
Carcinoma *in situ*	Yes	38 (49.4)	39 (50.6)	0.24
	No	43 (58.9)	30 (41.1)	
Lymphovascular invasion	Yes	32 (40.5)	47 (59.5)	0.001*
	No	49 (69)	22 (31)	
Smoker	Yes	30 (36.1)	53 (63.9)	0.001*
	No	51 (76.1)	16 (23.9)	
Hydronephrosis	Yes	30 (50)	30 (50)	0.42
	No	51 (56.7)	39 (43.3)	
Lymph node	N1-2	58 (60.4)	38 (39.6)	0.036*
	N0	23 (42.6)	31 (57.4)	
Clinical stage	T3–4	31 (53.4)	27 (46.6)	0.91
	T2	50 (54.3)	42 (45.7)	
AGR	>1.61	60 (90.9)	6 (9.1)	0.001*
	<1.61	21 (25)	63 (75)	
Sex	Female	19 (48.7)	20 (51.4)	0.44
	Male	62 (55.9)	49 (44.1)	
Albumin	>35	51 (58)	37 (42)	0.24
	<35	30 (48.4)	32 (51.6)	

χ^2 test
*Significant

Table 3. *Results of multivariate regression analyses*

	Response			
	P	OR	95% CI	
			Lower	Upper
Absence of LVI[a]	0.011*	3.398	1.331	8.672
Non-smoker[b]	0.014*	3.238	1.264	8.293
Absence of LN[c]	0.223	1.816	0.696	4.740
AGR >1.61	0.001*	23.024	8.148	65.062

[a]Presence of LVI
[b]Smoker
[c]Presence of lymph node
*Significant (p <0.005)
AGR – albumin-to-globulin ratio; LN – lymph node; LVI – lymphovascular invasion

Table 4. *Comparison of overall survival*

		Estimate	Std. Error	95% CI		P
				Lower	Upper	
Response	Non-responder	44.944	1.160	42.672	47.217	0.001*
	Responder	55.758	1.038	53.724	57.791	
CIS	Absence of CIS	53.804	1.235	51.384	56.224	0.002*
	Presence of CIS	50.892	1.251	45.891	50.796	
LVI	Absence of LVI	55.600	1.153	53.340	57.860	0.001*
	Presence of LVI	47.529	1.183	45.210	49.848	
HN	Absence of HN	51.417	1.250	48.966	53.867	0.67
	Presence of HN	50.367	1.336	47.748	52.985	
Smoke	Non-smoker	54.473	1.369	51.789	57.157	0.001*
	Smoker	47.862	1.100	45.706	50.017	
CS	T2	49.273	1.143	47.033	51.512	0.034*
	T3–T4	49.419	2.693	44.410	54.697	
LN	N0	49.333	1.626	46.146	52.521	0.26
	N1 + N2	51.731	1.092	49.590	53.872	
AGR	AGR <1.61	48.723	1.176	46.418	51.028	0.003*
	AGR >1.61	53.455	1.357	50.795	56.115	
Albumin	<35	49.000	1.423	46.210	51.790	0.069
	>35	52.243	1.170	49.949	54.537	

Log Rank Test
* Significant (p <0.005)
AGR – albumin to globulin ratio; CIS – Carcinoma in situ, CS – clinical stage, LVI – Lymphovascular invasion, HN – Hydronephrosis, LN – Lymph node

DISCUSSION

When choosing patients for NAC before cystectomy in MIBC, it is important to select cases where survival is low and to identify tumors that do not respond to chemotherapy. These tumors should be treated with early cystectomy to improve survival. This study showed that low AGR (<1.61) levels prior to neoadjuvant platinum-based chemotherapy were associated with a lower likelihood of response at subsequent RC. Our results suggest an association between inflammatory burden and chemosensitivity, and that patients with a high AGR (>1.61) for pure urothelial cancer have a higher chance of responding to NAC.

A total of four studies were conducted to evaluate the association of the NLR with pathological response in patients with MIBC who receive NAC [3-6]. In a study of 404 patients with NMIBC, Deimling et al. [4] found that elevated NLR was associated with a decreased probability of chemotherapy response. In another study, Black et al. [5] corroborated the hypothesis that high NLR is indicative of a suboptimal response to NAC, and that it functions as a poor prognostic indicator in patients undergoing NAC [5].

Table 5. *Results of Cox Regression Analysis*

	Overall survival			
	P	HR	95% CI	
			Lower	Upper
Response[a]	0.001*	5.346	2.304	12.402
CIS[b]	0.024*	1.925	1.088	3.405
LVI[c]	0.004*	2.677	1.367	5.244
No smoker[d]	0.034*	2.104	1.056	4.192
CS[f]	0.706	1.132	0.595	2.151
AGR >1.61	0.026*	2.418	1.113	5.252

[a]Non-responder
[b]Presence of CIS
[c]Presence of LVI
[d]Smoker
[e]>T2 stage *: significant (p <0.005)
AGR – albumin-to-globulin ratio; CIS – carcinoma *in situ*, CS – clinical stage, LVI – lymphovascular invasion

The predictive value of AGR in both MIBC and non-muscle-invasive bladder cancer (NMIBC) has been investigated. In a study of 364 patients with non-muscle invasive bladder cancer (NMIBC), Niwa et al. [13] found that low AGR was associated

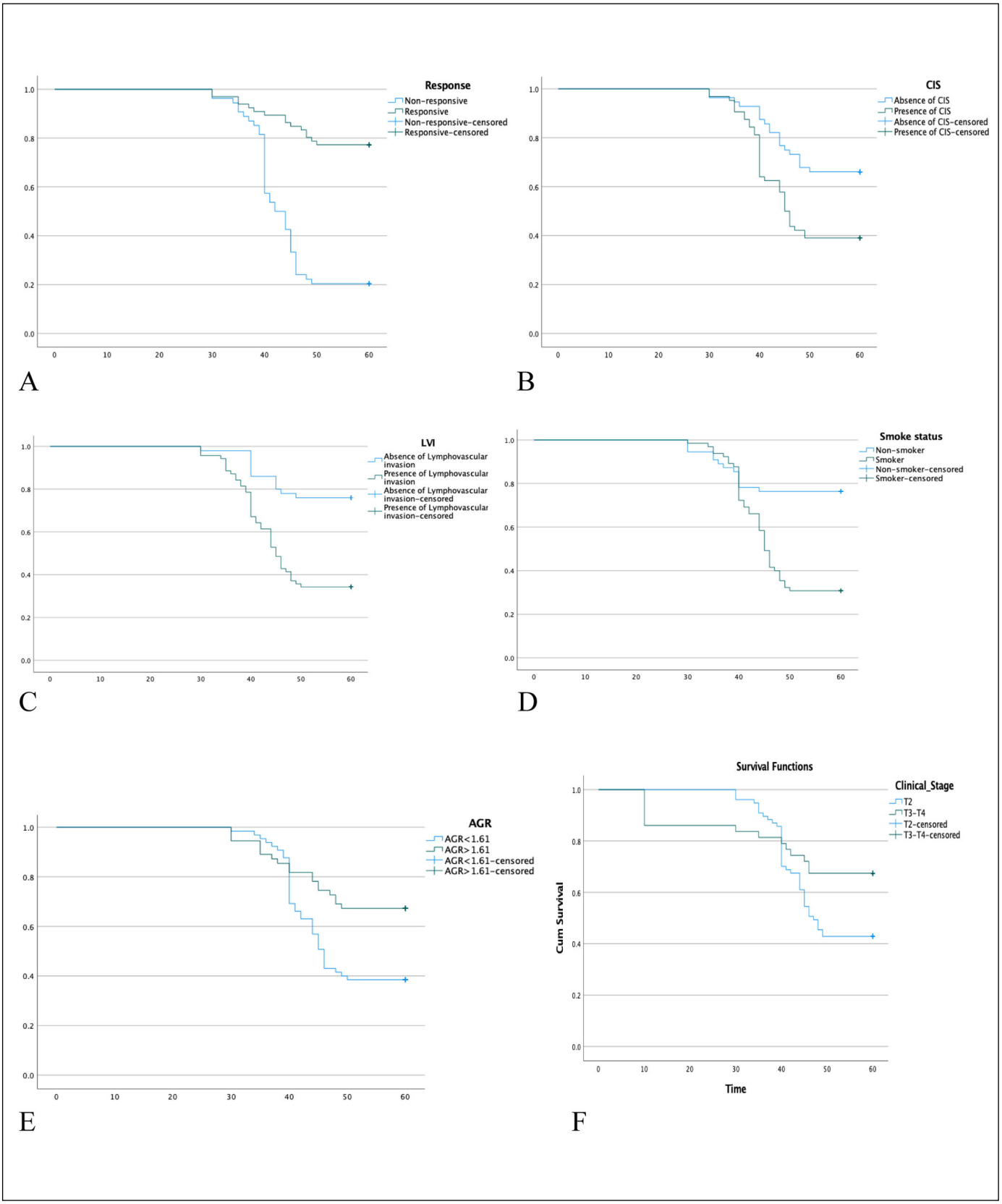


Figure 3. *The Kaplan-Meier survival curves are presented:* **A)** *those relating to NAC response status;* **B)** *those relating to CIS status;* **C)** *those relating to LVI status;* **D)** *those relating to smoking status;* **E)** *those relating to AGR;* **F)** *those relating to clinical stage for OS.*

with higher recurrence and progression rates. For muscle-invasive bladder cancer, a monocentric study that analyzed 296 patients who underwent RC found low AGR to be associated with worse recurrence-free survival and cancer-specific survival [14]. In these studies, similarly to our study, the cut-off for AGR was found to be 1.6. In a separate study, Schuettfort et al. [15] evaluated the association of preoperative AGR with survival in patients undergoing RC for bladder cancer. According to the results of their own research, they advanced the argument that low AGR is an independent predictor of ≥pT3 disease and may therefore assist in the identification of patients who are more likely to benefit from NAC [15].

The present study was conceived with the objective of investigating the accuracy of these predictions. To this end, the impact of AGR was evaluated using criteria for patient selection for NAC that are currently accepted, including molecular and genetic characteristics, as well as the presence of preoperative clinical high-risk factors such as hydronephrosis, high tumor stage, mixed histological features, and LVI [16]. In addition, an investigation was conducted into the impact of smoking on the efficacy of chemotherapy, owing to the ambiguity surrounding the existing literature on the subject [17]. Multivariate analysis indicated that non-smoking status, LVI negativity, lymph node absence, low clinical T stage, and high AGR (>1.61) were predictive of chemotherapy response. In univariate analysis, the absence of hydronephrosis and absence of CIS were effective on response, but these effects were not seen in multivariate analysis.

Since the albumin level can change due to many reasons such as poor nutritional state, impaired liver synthesis function, or conditions leading to excessive protein loss other than inflammation, we aimed to find a more reliable biomarker by comparing it with the globulin level, which is another parameter reflecting the inflammatory state. AGR reflects both inflammatory and nutritional status better than each factor alone, and therefore it may be a more useful predictor for patients with cancer [14, 18]. The present study investigates the effect of low albumin levels (<35 g/l) on chemotherapy response and overall survival. The investigation revealed no statistically significant disparity in albumin levels between patients who exhibited a positive response to chemotherapy and those who did not respond, suggesting that low albumin levels do not appear to influence the efficacy of chemotherapy. Furthermore, the study did not identify a correlation between low albumin levels and overall survival outcomes. While these findings appear to support the initial hypothesis, it is imperative to consider that the albumin levels measured in this study were taken prior to chemotherapy and surgical interventions.

The fact that this was a single-center study with a small number of patients and retrospective nature are limitations of our study. Also, the fact that our study was single-center, our hospital is not a cancer center, and we did not analyze patients with variant histology may have contributed to the low number of patients. However, an analysis of similar studies in the literature shows that the number of patients is similar. Due to the retrospective nature of this study, there is a possibility of selection bias; therefore, conclusions should be drawn with caution when evaluating the results. Despite these limitations, the results do not contradict the existing literature describing the relationship between inflammation and cancer. Another limiting factor is the lack of new approaches such as molecular and genetic analysis.

Consequently, the investigation of inflammatory markers as a means of selecting the appropriate patient for NAC is of paramount importance because these are less expensive and more readily accessible. The findings of this study suggest that a high AGR could serve as a prognostic indicator for chemotherapy response. The utilization of AGR in the selection of patients for NAC in the future may prove advantageous when compared with the use of genetic markers, which are costly when employed in conjunction with other predictive biomarkers if confirmed by other large-scale prospective studies.

Main points

In patients who do not respond to NAC, there is a risk of overtreatment and associated toxicity, as well as a risk of delaying potentially curative RC. This study showed that low AGR levels prior to platinum-based NAC were associated with a lower likelihood of response at subsequent RC.

This study was presented as an oral presentation at the 14th Eurasian Uro-oncology Congress.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

FUNDING

This research received no external funding.

ETHICS APPROVAL STATEMENT

The study was approved by the Ethics Committee (28.01.2025) of Prof. Dr. Cemil Tascioglu City Hospital in Istanbul (2025-41).

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