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Original Article

Factors influencing pathological response after neoadjuvant therapy for advanced gastric cancer

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Abstract: Objective: To identify the factors influencing pathological responses after neoadjuvant therapy in advanced gastric cancer and to construct an effective prediction model for an improved response. Methods: Clinical data from 100 patients with advanced gastric cancer who received neoadjuvant therapy at The Fifth Hospital of Wuhan from January 2020 to December 2023 were retrospectively analyzed. Basic data, laboratory test results, and other patient information were collected. Univariate and multivariate logistic regression were used to analyze the factors influencing good disease recovery after neoadjuvant therapy. Based on the results of multi-factor analysis, a nomogram risk prediction model was constructed, and its effectiveness was validated. The model's discriminatory power was assessed using the receiver operating characteristic curve (ROC) and the area under the ROC curve (AUC), while its fit was evaluated using a calibration curve. The model's consistency was assessed using the Hosmer-Lemeshow (HL) test. Results: Among the 100 patients, 22 (22%) had a good pathological response. Multivariate analysis showed that tumor differentiation, carcinoembryonic antigen (CEA), longest tumor diameter, and cN stage were significant factors influencing the pathological response of patients after neoadjuvant therapy. Based on the above indicators, a nomogram prediction model was constructed, with the following formula: Logit (P) = -1.653 + 1.562 × (tumor differentiation degree) + 1.925 × (CEA) + 1.620 × (longest tumor diameter) + 1.483 × (cN stage). The AUCs of the training set and the test set were 0.884 (95% CI: 0.778-0.990) and 0.861 (95% CI: 0.709-1.000), respectively. The HL test showed good fit (χ^2 = 4.939, P = 0.764). The calibration curve demonstrated that the predicted values closely matched the observed values. Conclusion: Tumor differentiation, CEA, longest tumor diameter, and cN stage are significant factors influencing the pathological response to neoadjuvant therapy in advanced gastric cancer. The prediction model developed based on these factors demonstrates good predictive performance and may aid in clinical decision-making.

Keywords: Advanced gastric cancer, neoadjuvant therapy, pathological reaction, nomograph

Introduction

Gastric cancer is a malignant tumor that poses a significant health threat to Chinese residents, with high morbidity and mortality [1]. Due to the lack of obvious early symptoms, most patients are diagnosed at an advanced stage. Although surgery remains the primary treatment, achieving radical cure through surgery alone is challenging. Therefore, a multidisciplinary approach combining surgery with chemotherapy, radiotherapy, targeted therapy, and immunotherapy has become the standard treatment for gastric cancer [2].

Among these treatments, neoadjuvant therapy has gained recognition as a key component of comprehensive treatment for locally advanced gastric cancer. This approach is recommended by the Chinese Society of Clinical Oncology (CSCO), the National Comprehensive Cancer Network (NCCN), and the European Society for Medical Oncology (ESMO) guidelines [3]. Neoadjuvant therapy not only helps assess the sensitivity to radiotherapy and chemotherapy but also facilitates tumor shrinkage, reduces tumor stage, and increases the likelihood of surgical resection. Furthermore, it plays a crucial role in preventing the formation of drug-resistant cell lines and reducing postoperative recurrence and metastasis [4].

The survival benefit of neoadjuvant therapy is related to the tumor's pathological response, defined as the proportion of residual tumor cells in the resected specimen after neoadju-

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vant therapy. A good pathological response means that the tumor is sensitive to neoadjuvant therapy, leading to better disease control, improved surgical resection rates, and enhanced survival outcomes [5]. However, there is considerable variability in pathological responses among patients, influenced by factors such as clinical characteristics, tumor biology, treatment strategies, and drug sensitivity [6]. Therefore, identifying the factors affecting the pathological response to neoadjuvant therapy is of great clinical value. By recognizing patients who are sensitive to neoadjuvant therapy, more accurate and individualized treatment plans can be developed for gastric cancer. Currently, studies on the factors influencing pathological responses to neoadjuvant therapy in advanced gastric cancer are inconsistent, with most focusing on specific factors or treatment methods [7]. To address this, our study comprehensively analyzed patient characteristics and carried out a multi-factor comprehensive analysis, avoiding the limitations of single-factor studies. Additionally, we have developed and internally validated a nomogram risk prediction model based on the results of this analysis. This model aims to predict pathological response accurately, providing a reliable tool for clinical decision-making in neoadjuvant therapy.

The goal of this study is to collect and analyze clinical data from patients with advanced gastric cancer undergoing neoadjuvant therapy and to develop and validate a nomogram prediction model to identify those likely to have a good pathological response. This model can serve as a practical and accurate tool for clinicians in decision-making regarding neoadjuvant therapy.

Materials and methods

General information

A total of 100 patients with advanced gastric cancer who received neoadjuvant therapy at The Fifth Hospital of Wuhan from January 2020 to December 2023 were retrospectively selected as the study subjects.

Inclusion criteria: (1) Pathologically confirmed gastric cancer [8]. (2) CT examination conducted within 1 week before treatment. (3) Gastrectomy performed after neoadjuvant therapy according to the established scheme, and postoperative pathological data available. (4) No distant metastasis. Exclusion criteria: (1) History of abdominal surgery; (2) Presence of other malignant tumors. (3) Inadequate imaging due to partial stomach filling or unclear lesions. (4) Presence of motion artifacts in the imaging that interfered with evaluation. The patients were randomly divided into the training set (70 cases) and the test set (30 cases) by 7:3. The training set was used to construct the nomogram risk prediction model, and the test set was used to verify the model performance. There was no significant difference between the sets. This study was approved by the Ethics Committee of The Fifth Hospital of Wuhan.

Treatment methods

Neoadjuvant chemotherapy regimens were adopted: (1) SOX regimen: Tiggio capsule (S-1), 80 mg/m^2, orally, twice a day for 1 to 14 days; Oxaliplatin, 130 mg/m^2, intravenous infusion on day 1; Treatment cycle: 21 days. (2) FLOT regimen: 5-fluorouracil, 2600 mg/m^2, continuous intravenous infusion for over 24 hours on day 1; Calcium folinate, 200 mg/m^2, intravenous infusion on day 1; Oxaliplatin, 85 mg/m^2, intravenous infusion on day 1; Docetaxel, 50 mg/m^2, intravenous infusion on day 1; Treatment cycle: 14 days. Chemotherapy cycles were ≥ 2, with some patients receiving radiotherapy or immunotherapy before surgery. After tumor shrinkage, patients underwent radical gastrectomy with D_2 or D_{2+} lymph node dissection, and combined organ resection was performed when necessary to ensure R_0 resection.

Neoadjuvant concurrent chemoradiotherapy: (1) Induction chemotherapy: SOX regimen was administered for 2 to 4 cycles with specific doses as described above. (2) Concurrent chemoradiotherapy: Three-dimensional conformal intensity-modulated radiotherapy with planned target area of 40.04 Gy/22f, or planned tumor target area of 45.1 Gy/22f; simultaneous oral administration of Tiggio capsule, 80 mg/m^2, once a day.

Outcome measurements

Primary measures: The primary outcome was the pathological response of advanced gastric

cancer patients after neoadjuvant therapy. Postoperative pathological specimens were graded according to Becker grading criteria [9]. Grade 1a: no residual tumor cells; Grade Ib: < 10% residual tumor cells; Grade 2: 10% to 50% residual tumor cells; Grade 3: > 50% residual tumor cells. In this study, patients with grades Ia and Ib were classified into the Good Pathological Response (GR) group. Patients with grades 2 and 3 were classified into the Poor Response (PR) group. Secondary measures: Secondary variables included age, gender, drinking history, smoking history, body mass index (BMI), longest tumor diameter, tumor location, tumor differentiation degree, tumor stage, carcinoembryonic antigen (CEA), neoadjuvant therapy type. Tumor size was determined by endoscopic ultrasonography (EUS). Patients were staged according to the 8th edition of American Joint Committee on Cancer (AJCC) TNM staging system for gastric cancer before chemotherapy. Clinical T and N stages were determined according to CT examination before chemotherapy.

Follow-up visit

The follow-up started on the date of treatment and continued every 3 months. If any special discomfort occurred, follow-up visits were conducted as needed. Routine follow-up included routine blood work, complete biochemical panels, tumor markers, whole abdominal CT, and gastroscopy one year after surgery. The final follow-up date was June 30, 2024.

Statistical methods

RStudio software and SPSS 23.0 statistical software were used for data analysis. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$) and compared between groups using two independent samples t-tests. Count data were expressed as the number of cases and percentage [n (%)], and the χ^2 test was used for comparison between groups. Logistic regression analysis was conducted to identify influencing factors. P< 0.05 was considered statistically significant. The data were randomly divided into the training set and the test set in a 7:3 ratio. The training set is used to construct the nomogram risk prediction model, and the test set is used to verify the model performance. The model's discrimination was evaluated using the ROC curve and calibration curve. The goodness of fit was assessed using the Hosmer-Lemeshow test, with P > 0.05 indicating good consistency.

Results

Comparison of general data between the two groups

According to the postoperative pathological response evaluation, 22 out of 100 patients (22%) achieved GR. There were significant differences between the GR group and the PR group in tumor differentiation, CEA levels, longest tumor diameter, and cN stage (all P< 0.05). However, no significant differences were observed for other indicators (all P > 0.05), as shown in **Table 1**.

Multivariate analysis

Variables with statistical significance in univariate analysis were included as independent variables, with the presence of GR as the dependent variable (yes = 0, no = 1). The variable assignment table is shown in **Table 2**. The results showed that tumor differentiation, CEA, the longest tumor diameter, and cN stage were independent factors influencing pathological response to neoadjuvant therapy. Specifically, patients with earlier tumor cN stage, smaller tumor size, lower CEA levels, and better tumor differentiation had better pathological responses to neoadjuvant therapy (**Table 3**).

Predictive value of tumor differentiation, CEA, longest tumor diameter, and cN stage for pathological response after neoadjuvant therapy

ROC curve analysis showed that AUC obtained by combining all four factors was significantly higher than those obtained by using tumor differentiation, longest diameter, cN stage, or CEA level alone (P< 0.05) (**Table 4**). The ROC curves for tumor differentiation, longest tumor diameter, cN stage, CEA level, and combined detection are shown in **Figure 1**.

Nomogram model

A column-line risk model was developed based on the results of the multivariate analysis, including the four identified influencing factors, using data from 70 patients in the training set

Table 1. Comparison of clinical data between the two groups [n (%), ($\bar{x}$±s)]

Factors	GR group (n = 22)	PR group (n = 78)	χ^2/t	*P*
Age (years)	58.68±8.81	57.23±8.28	0.716	0.476
BMI (kg/m^2)	23.62±0.92	23.36±1.36	1.055	0.297
Gender				
Female	10 (45.45)	34 (43.59)	0.024	0.876
Male	12 (54.55)	44 (56.41)		
Drinking				
No	14 (63.64)	39 (50.00)	1.281	0.258
Yes	8 (36.36)	39 (50.00)		
Smoking				
No	9 (40.91)	39 (50.00)	0.568	0.451
Yes	13 (59.09)	39 (50.00)		
Tumor location				
Upper stomach	4 (18.18)	15 (19.23)	0.027	0.987
Middle stomach	8 (36.36)	29 (37.18)		
Lower stomach	10 (45.45)	34 (43.59)		
Degree of tumor differentiation				
Moderately/highly differentiated	15 (68.18)	23 (29.49)	10.905	0.001
Poorly differentiation	7 (31.82)	55 (70.51)		
CEA (μg/L)				
≤ 5	17 (77.27)	25 (32.05)	14.406	< 0.001
> 5	5 (22.73)	53 (67.95)		
longest tumor diameter (cm)				
< 4	18 (81.82)	29 (37.18)	13.727	< 0.001
≥ 4	4 (18.18)	49 (62.82)		
Methods of treatment				
Chemotherapy	10 (45.45)	37 (47.44)	0.027	0.869
Chemoradiotherapy	12 (54.55)	41 (52.56)		
cT staging				
cT_3	13 (59.09)	33 (42.31)	1.946	0.163
cT_4	9 (40.91)	45 (57.69)		
cN staging				
cN_0	17 (77.27)	30 (38.46)	10.399	0.001
cN_+	5 (22.73)	48 (61.54)		

Note: CEA: carcinoembryonic antigen.

Table 2. Factor assignment table

Factor	Assign
Tumor differentiation	0 = Moderately/highly differentiated, 1 = poorly differentiation
CEA	≤ 5 = 0, > 5 = 1
Longest tumor diameter	< 4 = 0, ≥ 4 = 1
cN stage	cN_0 = 0, cN_+ = 1

Note: CEA: carcinoembryonic antigen.

(**Figure 2**). The specific prediction formula is: Logit (P) = -1.653 + 1.562 × (tumor differentiation degree) + 1.925 × (CEA) + 1.620 × (longest tumor diameter) + 1.483 × (cN stage). To obtain the corresponding score, project each variable's points onto the "points" axis, then sum the scores. The total score corresponds to the predicted result.

Table 3. Logistic analysis of pathological response after neoadjuvant therapy in gastric cancer patients

Variable	B	SE	Wald	*P*	OR (95% CI)
Tumor differentiation	1.562	0.637	6.006	0.014	4.768 (1.367-16.629)
CEA	1.925	0.679	8.029	0.005	6.853 (1.810-25.944)
Longest tumor diameter	1.620	0.681	5.664	0.017	5.054 (1.331-19.194)
cN stage	1.483	0.678	4.778	0.029	4.406 (1.166-16.655)

Note: CEA: carcinoembryonic antigen.

Table 4. ROC curve analysis

Variable	AUC	Sensitivity	Specificity	95% CI	*P* value
Combined detection	0.880	93.6%	68.2%	0.800-0.960	<0.001
Tumor differentiation	0.693	70.5%	68.2%	0.566-0.821	0.006
CEA	0.726	67.9%	77.3%	0.607-0.845	0.001
Longest tumor diameter	0.723	62.8%	81.8%	0.608-0.839	0.001
cN stage	0.694	61.5%	77.3%	0.573-0.815	0.006

Note: CEA: carcinoembryonic antigen.

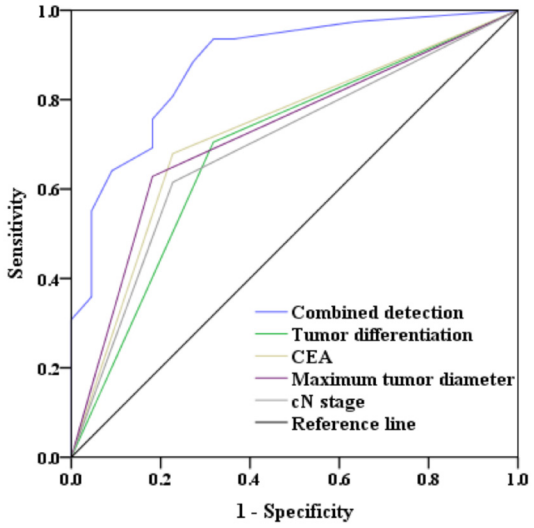

Figure 1. ROC curve analysis of different indexes. *Note:* CEA: carcinoembryonic antigen.

Analysis of the Nomogram's predictive value for pathological response after neoadjuvant therapy

To further verify the predictive efficiency of the model, ROC curves for both the training set and test set were plotted (**Figure 3**). The model demonstrated high accuracy in both sets, with AUCs of 0.884 (95% CI: 0.778-0.990) for the training set and 0.861 (95% CI: 0.709-1.000) for the test set. The HL test showed a good fit (χ^2 = 4.939, P = 0.764). The calibration curve (**Figure 4**) shows that the nomogram's prediction probability has a good agreement between the training set and the test set.

Survival analysis

Patients in the two groups were followed for 24 to 54 months. Overall survival (OS) in the GR group was significantly higher than that in the PR group, with a median OS of 51 months in the GR group and 44 months in the PR group (χ^2 = 4.351, P = 0.037, **Figure 5**).

Discussion

The comprehensive treatment of gastric cancer has become widely accepted. Neoadjuvant therapy is recommended by major guidelines due to its advantages, including good patient compliance, elimination of micrometastasis, tumor downstaging, and improved surgical resection rates [10]. Studies have shown that neoadjuvant therapy significantly improves survival rates in patients with advanced gastric cancer [11, 12]. It has also been found to induce tumor shrinkage and increase the R0 resection rate in these patients [13]. As neoadjuvant therapy becomes more widely accepted, understanding how to objectively assess its effects and predict patient prognosis has become a key area of research. Oncologic pathological response is considered one of the most important indicators in this regard. Several studies suggest that gastric cancer patients achieving pathological complete res-

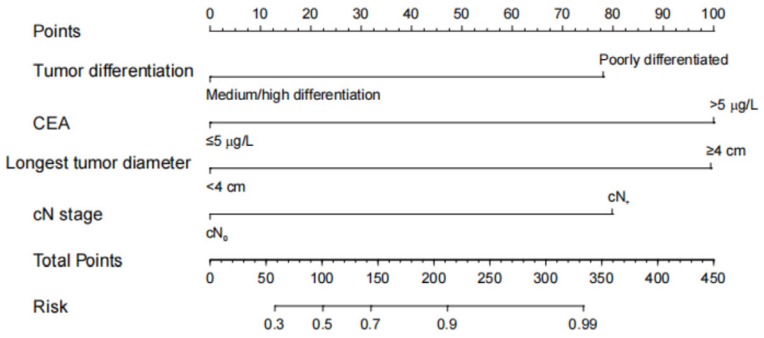

Figure 2. Nomogram prediction model. *Note:* CEA: carcinoembryonic antigen.

ponse (pCR) after neoadjuvant therapy have a better prognosis and survival [14]. In this study, the overall rate of good pathological response after neoadjuvant therapy was 22% (22/100). Sun's study [15] reported a pCR rate of 26.5% for neoadjuvant concurrent chemoradiotherapy. A meta-analysis [16] conducted in China showed that the average pCR rate across seven studies on neoadjuvant therapy for gastric cancer was 6.74% (3%-15%). Although perioperative comprehensive treatment has become the standard for the treatment of locally advanced gastric cancer, the pathological responses reported by various studies are unique due to the different standards of neoadjuvant treatment (chemotherapy or chemoradiotherapy), application of chemotherapy regimens, and clinical and pathological characteristics of enrolled patients.

The relationship between the degree of tumor differentiation and pCR rate after neoadjuvant therapy has been repeatedly demonstrated in related studies of gastric cancer. The higher the degree of tumor differentiation before neoadjuvant therapy, the more likely to achieve a complete response. The results of this study showed that the degree of tumor differentiation was an influencing factor of the pathological response to neoadjuvant therapy in patients with advanced gastric cancer, which further verified this view and suggested that the well-differentiated tumor had a better pathological response to neoadjuvant therapy. Shao [17] et al. showed that patients with well-differentiated tumors before treatment were more likely to achieve GR. The possible reason is that well-differentiated tumors have a relatively low cell proliferation rate while retaining more normal cell characteristics, including the ability to metabolize and expel drugs, so they are more sensitive to cell cycle inhibitors (such as chemotherapeutic drugs), which helps to improve the effectiveness of chemotherapeutic drugs. The results of this study showed that tumor length was a predictor of good pathological response after neoadjuvant therapy, which was consistent with the results of Li [18]. The possible reason is that a smaller tumor means a smaller overall volume, which facilitates more uniform penetration of chemotherapy drugs into the tumor tissue, thereby improving the effectiveness of treatment. In addition, tumors of shorter length may have a slower growth rate, lower invasiveness, and metastatic potential, and at the same time be more amenable to surgical resection

The results of the present study showed that GR was more likely to be achieved in patients with low CEA levels. Increased CEA levels are considered to be associated with heavier tumor burden and faster tumor growth rate, and also lead to decreased sensitivity to chemotherapy [19]. Chen [20] showed that higher lymphocyte ratio and carcinoembryonic antigen (CEA) level, lower monocyte count, and tumor differentiation grade correlated with higher pathological complete response. In addition, the results of this study showed that cN stage was also an important factor affecting the pathological response, suggesting that patients with earlier cN stage and smaller tumor burden were more sensitive to neoadjuvant therapy, which was consistent with the results of Lombardi [21]. The mechanism may be that the cN stage is related to tumor burden and invasiveness [22]. Liang et al. [23] showed that patients with a relatively late cN stage had a lower probability of achieving pCR, and patients with a relatively late cN stage had to bear a greater risk of neoadjuvant therapy. Therefore, it is of great significance to detect the degree of tumor differentiation, the longest diameter of the tumor, cN stage, and CEA level in predicting the pathological response to neoadjuvant therapy in patients with advanced gastric cancer. According to the ROC curve analysis, it was found that the AUG of combined detection of tumor differentiation, tumor longest diameter, cN stage, and CEA le-

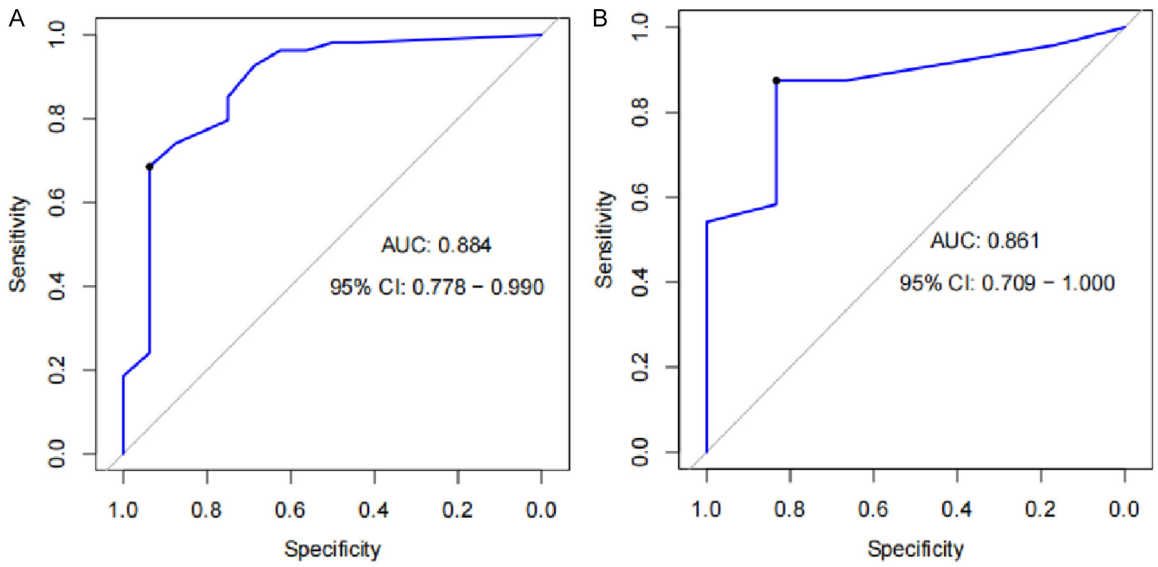

Figure 3. ROC curve. *Note:* A: Training set; B: Test set.

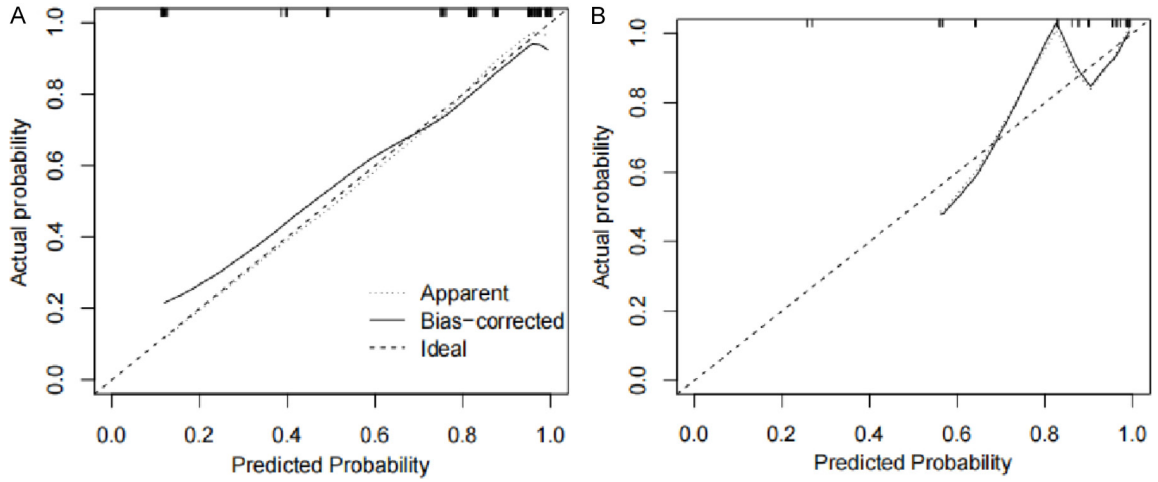

Figure 4. Calibration curves for the prediction effect of the nomogram model. *Note:* A: Training set; B: Test set.

vel was 0.880 (95% CI was 0.800-0.960, P< 0.001), which was significantly higher than that of tumor differentiation, tumor longest diameter, cN stage and CEA level alone. The combined detection of the four influencing factors helps predict and evaluate the condition of patients, which is of great significance for early intervention and treatment of clinical patients.

In addition, a nomogram risk prediction model was constructed according to the influencing factors, which was used to predict the risk, and the ROC curve was drawn to evaluate the discrimination of the model. The nomogram is composed of tumor differentiation degree, longest tumor diameter, cN stage, and CEA level, which has high reliability and clinical practicability. The AUC values of the test set and validation set of the model were 0.884 (95% CI: 0.778-0.990) and 0.861 (95% CI: 0.709-1.000), respectively, and the AUC values of the two data were > 0.8, indicating that the nomogram had good discrimination. It can be seen from the results of this study that the prediction model of pathological response to neoadjuvant therapy in patients with advanced gastric cancer is successfully established, and the internal validation of the prediction performance and consistency of the model is completed, which can assist clinicians in decision-making. In

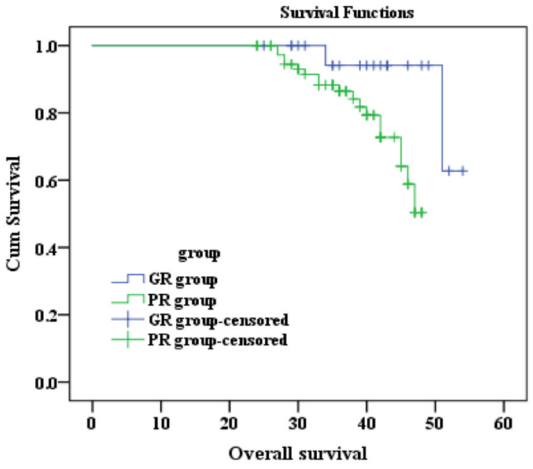

Figure 5. Survival curve.

addition, from the prognostic results of this study, the OS of patients in the GR group was significantly longer than that in the PR group, suggesting that GR is not only an effective indicator of the short-term efficacy of neoadjuvant therapy but also a good judge of the survival of patients. This conclusion is consistent with previous clinical studies [24].

In conclusion, cN stage, tumor length, CEA, and tumor differentiation degree were the influencing factors of a good pathological response to neoadjuvant therapy in patients with advanced gastric cancer, and a nomogram was constructed to predict good pathological responses. The nomogram has been verified to have a high predictive ability, which is conducive to the formulation of individualized treatment strategies for different types of patients in the future. However, due to the limitation of the number of cases, the restriction of retrospective analysis studies, the long period of patient data collection, and the lack of differentiation between the effects of different chemotherapy regimens on the prognosis of patients, these may affect the accuracy of the model to some extent, but our preliminary study results will provide a certain basis for upcoming research. In the future, multi-center prospective studies with large samples should be conducted to further verify the accuracy of the prediction model, and multifactor prediction models combining clinical examination, imaging, molecular characteristics, gene loci, and other factors should be established to more accurately guide the prognosis of patients with advanced gastric cancer.

Disclosure of conflict of interest

None.

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