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Development and validation of a metabolic syndrome and its components to predict the efficacy of neoadjuvant chemotherapy in breast cancer

An observational, single-center, cohort study

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Abstract

To assess whether metabolic syndrome can be used as a reference index to evaluate the efficacy of neoadjuvant chemotherapy treatment for breast cancer (BC). Seventy cases of female BC patients who received neoadjuvant chemotherapy treatment and surgical treatment at the Glandular Surgery Department of Hebei Provincial People's Hospital from January 2021 to December 2023 were retrospectively collected, and clinical data such as puncture pathology were recorded. The clinical data were analyzed by 1-way analysis using the χ^2 test, and further multifactorial logistic regression analysis was performed for statistically significant differences. The independent risk factor metabolic syndrome (MetS) and its components were plotted in the receiver operating characteristic curve (ROC) curve and baseline graph by R Studio 4.41 software, and the meaningful components were plotted in the column graph by lasso regression analysis for internal validation, and the quality of the model was evaluated by the ROC curve and calibration graph, and then the clinical decision curve analysis was used to evaluate the clinical effectiveness of the model. The neoadjuvant efficacy was statistically associated with whether the patient was first diagnosed between 45 and 55 years of age, estrogen receptors (ER), progesterone receptors (PR) expression status, Her-2 expression status, and whether the patient had MetS, as determined by univariate analysis through χ^2 ($P < .05$). On multifactorial binary logistic regression analysis, ER, PR status, Her-2 status, and the presence of MetS were statistically significant ($P < .05$) for the efficacy of neoadjuvant chemotherapy. Patients with MetS were less likely to achieve complete pathological remission than those without MetS. MetS and its components were analyzed by lasso regression analysis with RStudio 4.41 software to conclude that hypertension, hyperglycemia, and high-density lipoprotein were all correlates affecting the pathologic complete response (pCR), and a column-line graph was plotted, with a C-index of 0.76, indicating a good predictive efficacy. ER, PR status, Her-2 status and the presence of MetS are independent predictors for assessing the efficacy of neoadjuvant chemotherapy in BC, and MetS can be used as a predictor of the efficacy of neoadjuvant chemotherapy. Clinical references are provided.

Abbreviations: AUC = area under the curve, BC = breast cancer, BG = blood sugar, BMI = body mass index, BP = blood pressure, DCA = decision curve analysis, ER = estrogen receptors, HDL = low-density lipoprotein, LTCS = long-term cancer survivors, MetS = metabolic syndrome, NACT = neoadjuvant chemotherapy, OBC = occult BC, pCR = pathologic complete response, PR = progesterone receptors, ROC = receiver operating characteristic curve, WC = waist circumference.

Keywords: line drawing, metabolic syndrome, neoadjuvant chemotherapy for BC

Written informed consent was obtained from the patient for publication of this study.

The authors have no funding and conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

The case data used in this study have been reviewed and approved by the Medical Ethics Committee of Hebei Provincial People's Hospital (No. 2024-LW-0154).

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1. Introduction

Background: Most of the patients who need neoadjuvant therapy for breast cancer (BC) are in the middle or late stage, and their condition is more critical. Failure to apply the appropriate chemotherapy regimen in a timely and effective manner may delay the disease and prevent the progression of the tumor.

Problem definition: This study focuses on the impact of metabolic syndrome (MetS) on the efficacy of neoadjuvant chemotherapy, and aims to improve the pathologic complete response (pCR) rate after neoadjuvant treatment by improving the MetS.

Literature review: It is now formalized that MetS is associated with a variety of in tumor development and progression, but its impact on the efficacy of neoadjuvant therapy in BC is currently unknown, and so this was looked at in this study.

Aims and contributions of the study: The aim was to assess whether MetS can be used as a reference index to evaluate the efficacy of neoadjuvant chemotherapy treatment in BC. In order to improve the survival rate and quality of life of patients. So we collected the existing clinical data and went to predict the efficacy of neoadjuvant chemotherapy through retrospective study, thus giving a more optimal treatment to the patients. MetS can be used as an indicator to predict the efficacy of neoadjuvant chemotherapy through statistical analysis. A more reliable risk prediction model was also constructed, which provides a reference for clinical practice.

BC has become the number 1 public enemy threatening women's health. The annual incidence of BC is about 0.145% and the mortality rate is about 0.033%. It has become the leading cause of death in women aged 45 to 55 years.[1] It is expected to increase to more than 3 million new cases and 1 million deaths per year after 2024 due to population growth and aging alone.[2] Based on the current situation the treatment of BC is particularly important, and neoadjuvant chemotherapy (NACT), as an important part of the overall treatment of BC, sometimes delays the treatment of the disease due to the uncertainty of its efficacy.

In recent years, with the strengthening of people's health awareness, the attention to obesity, high blood glucose, high blood lipids, high blood pressure (BP), and other indicators has also risen, and thus the concept of MetS has gradually come into the public's field of vision. The prevalence of MetS has been found to increase with age, with a prevalence of up to 37% in women aged 40 to 59 years and up to 54% in women aged 60 years and above.[3] It is due to the fact that both BC and MetS have an increased prevalence with age, while a growing number of studies have shown that MetS is associated with an increased risk of developing a variety of malignancies and a poor prognosis.[4–7] So assessing whether MetS can be used as a prognostic indicator for neoadjuvant chemotherapy of BC and whether it can provide a reference basis for clinical diagnosis and treatment became the research purpose of this paper. However, there are fewer studies on the correlation between BC and MetS, and this paper aims to explore the impact of assessing MetS on the prognosis of BC patients by investigating the correlation between pCR and clinical features after NACT for BC.

2. Study data and efficacy evaluation

2.1. Study subjects

Seventy-three female BC patients who underwent NACT and surgical treatment at the Glandular Surgery Department of Hebei Provincial People's Hospital from January 2021 to December 2023 were retrospectively collected, of which 3 patients were occult BC (OBC), and the remaining 70 patients were included in this study. Inclusion criteria: Preoperative neoadjuvant chemotherapy without radiotherapy or endocrine therapy; pathological diagnosis of BC by hollow needle aspiration before chemotherapy; completion of surgical treatment. Exclusion criteria: incomplete clinicopathological and/or auxiliary examination data; OBC; factors affecting the results of blood tests before neoadjuvant chemotherapy, such as taking special drugs. Patients signed the hospital's "informed consent for secondary use of cases" after admission. This study has passed the approval of scientific research papers involving human biomedical and animal experiments by the Medical Committee of Hebei Provincial People's Hospital (No. 2024-LW-0154).

2.2. Research data

The patients' body mass index (BMI) and waist circumference at the time of their first hospitalization were collected; the average of 3 measurements of BP at quiet rest after admission; fasting blood glucose, fasting triglycerides (TG), fasting high-density lipoprotein cholesterol; previous diagnosis of hypertension and/or diabetes mellitus; menopausal or not; the clinical puncture pathology data for the first diagnosis of BC; the imaging data for the first diagnosis of BC; and the postoperative paraffin wax pathological results [MP grading, estrogen receptors (ER), progesterone receptors (PR), Her-2, Ki-67].

The diagnosis of MetS was performed according to the diagnostic criteria for MetS in the Chinese Clinical Guidelines for Prevention and Control of Type 2 Diabetes in the Elderly (2022 edition).[8] Those with 3 or all of the following 4 components: Overweight and/or obesity BMI ≥ 25.0 kg/m^2. Hyperglycemia FPG ≥ 6.1 mmol/L (110 mg/dL) and/or 2hPG ≥ 7.8 mmol/L (140 mg/dL), and/or those who have been diagnosed and treated for diabetes. Hypertension SBP/DBP ≥ 140/90 mm Hg, and/or those who have been diagnosed and treated for hypertension. Dyslipidemia fasting blood TG ≥ 1.7 mmol/L (110 mg/dL), and/or fasting blood HDL < 0.9 mmol/L (35 mg/dL) (male), <1.0 mmol/L (39 mg/dL) (female).

2.3. Evaluation of therapeutic efficacy

According to the Miller/Payne grading system adopted by the Department of Pathology of our hospital for postoperative specimens of NACT patients.[9] Grade 1 (G1): invasive cancer cells are unaltered or only individual cancer cells are altered, and there is no overall reduction in the number of cancer cells; grade 2 (G2): mild reduction in invasive cancer cells, but the total number of cells is still high, and the reduction in the number of cancer cells is not more than 30%; and grade 3 (G3): between 30% and 90%; grade 4 (G4): significant reduction of invasive cancer cells by more than 90%, with only scattered small clusters of cancer cells or single cancer cells remaining; grade 5 (G5): there are no more invasive cancer cells at the original tumor bed site, but ductal carcinoma in situ may be present. In this study, the efficacy was classified into 2 groups, pCR and non-PCR, according to the MP grading system. g5 was pCR, while the rest of G1, G2, G3 and G4 were regarded as non-PCR.

2.4. Statistical methods

SPSS 27.0 (Chicago) statistical software was used to analyze the data, and the count data were statistically described by frequency or frequency n (%), and the χ^2 test was used for comparison between groups. Multifactor were analyzed using binary logistic regression analysis to study the independent risk factors affecting the efficacy of NACT. Measurement data conforming to normal distribution were expressed as ($\bar{x} \pm s$) by R Studio 4.41 software, and *t*-test was performed for comparison between groups; non-normally distributed data were expressed as M (P25, P75), and rank-sum test was performed for comparison between groups; and the count data were compared by the χ^2 test. The MetS and its components were plotted by producing receiver operating characteristic curve (ROC) and baseline plot respectively, and the area under the curve (AUC) was visualized in the form of histogram, and the meaningful components were

screened by lasso regression analysis to plot the column-line graph, and the patients included in the study were randomly divided into the training set and the validation set at a ratio of 7:3 and the ROC curves and the calibration curve graphs were plotted respectively to the ROC curve and calibration curve were plotted to reflect the consistency of the model, and then the clinical effectiveness of the model was evaluated by clinical decision curve analysis (DCA). $P < .05$ was regarded as statistically significant.

3. Results

3.1. Comparison of clinical data between pCR group and non-PCR group

A total of 70 study subjects were included in this study, all of them were female, aged 32 to 75 years, and the age was divided into 2 groups, the high-incidence age group and other age groups, according to the high-incidence age group of BC, 45 to 55 years. Menopausal status was determined according to the results of hormone 6. Tumor size and molecular biomarkers were determined by preoperative breast nuclear magnetic and aspiration pathology results. Each case was diagnosed according to the diagnostic criteria of MetS in the Chinese Clinical Guidelines for Prevention and Control of Type 2 Diabetes in the Elderly (2022 edition). There were 27 patients (38.57%) with MetS and 43 patients (61.43%) without MetS. The postoperative pathological MP grading of the collated patients, of which 29 patients (41.42%) achieved pCR (G5); 31 patients (44.28%) were non-pCR (G1 + G2 + G3 + G4). Univariate analysis by x^2 yielded a statistically significant relationship between NACT efficacy and whether the patients were between 45 to 55 years of age at first diagnosis, hormone receptor (ER, PR) expression status, Her-2 expression status, and whether they suffered from MetS ($P < .05$), while there was no statistically significant relationship with whether they were in menopausal status, T-stage, and Ki-67 ($P > .05$), as shown in Table 1.

3.2. Multifactorial analyses affecting neoadjuvant efficacy in BC patients

The 4 independent risk factors of age at first diagnosis, ER, PR status, Her-2 status, and whether or not they have MetS, which were statistically significant, were subjected to multifactorial binary logistic regression analysis. The results showed that ER, PR status, Her-2 status and the presence of MetS had a statistically significant effect on the efficacy of NACT ($P < .05$). Patients with MetS were less likely to obtain pCR than those without MetS; hormone receptor-positive patients were more likely to obtain pCR than hormone receptor-negative patients; and Her-2-positive patients were likewise more likely to obtain pCR than Her-2-negative patients, as shown in Table 2.

3.3. Predictive modeling and validation of MetS and its components in relation to pCR rate after NACT in patients

In this study, MetS was considered as an independent risk factor affecting pCR, so it was further investigated whether the components of MetS were statistically significant ($P < .05$) for pCR respectively. The R Studio 4.4.1 software was used to draw the ROC to determine the predictive value of MetS and its components on whether pCR could be achieved in BC patients after NACT. The AUC was also visualized as a histogram (Figs. 1A and 2). AUC = 0.712 for MetS, AUC = 0.665 for whether or not suffering from blood glucose > 6.0 mmol/L, AUC = 0.663 for HDL < 1.0 mmol/L, AUC = 0.655 for BMI ≥ 25.0 kg/m^2, AUC = 0.563 for TG ≥ 1.7 mmol/L,

Table 1

Comparison of clinical data between the pCR group and the non-PCR group.

Factors		n	(%)	pCR	Non-pCR	χ^2	*P*
Age at diagnosis	≥45 and ≤55	39	(55.71%)	11	28		
	Remaining age	31	(44.29%)	18	13	6.346	.012
T state	T1	7	(10%)	2	5		
	T2	35	(50%)	16	19		
	T3	19	(27.14%)	9	10	2.386	.496
	T4	9	(12.86%)	2	7		
Menopausal state	Menopausal	39	(55.71%)	17	22		
	No menopausal	31	(44.29%)	12	19	0.170	.681
ER, PR state	Positive	42	(60%)	22	201	5.191	.023
	Negative	28	(40%)	7	21		
Her-2 state	Positive	35	(50%)	19	16	4.769	.029
	Negatives	35	(50%)	10	25		
Ki-67 index	≤14%	12	(17.14%)	72	5	1.706	.192
	>14%	58	(82.86%)	2	36		
MetS	Fall ill	27	(38.57%)	4	23	12.830	<.01
	Disease-free	43	(61.43%)	25	18		

Abbreviations: MetS = metabolic syndrome, pCR = pathologic complete response.

Table 2

Multifactorial analysis affecting the efficacy of neoadjuvant therapy in breast cancer patients.

Variable	*B*	Standard error	Wald	Df	*P*	OR	95% CI
Age at diagnosis	0.407	0.683	0.355	1	.551	1.503	0.394 to 5.737
ER, PR state	−1.725	0.660	6.834	1	.009	0.178	0.049 to 0.649
Her-2 state	1.088	0.505	4.641	1	.031	2.969	1.103 to 7.990
MetS	2.539	0.714	12.651	1	<.001	12.665	3.126 to 51.308

Abbreviations: ER = estrogen receptors, PR = progesterone receptors.

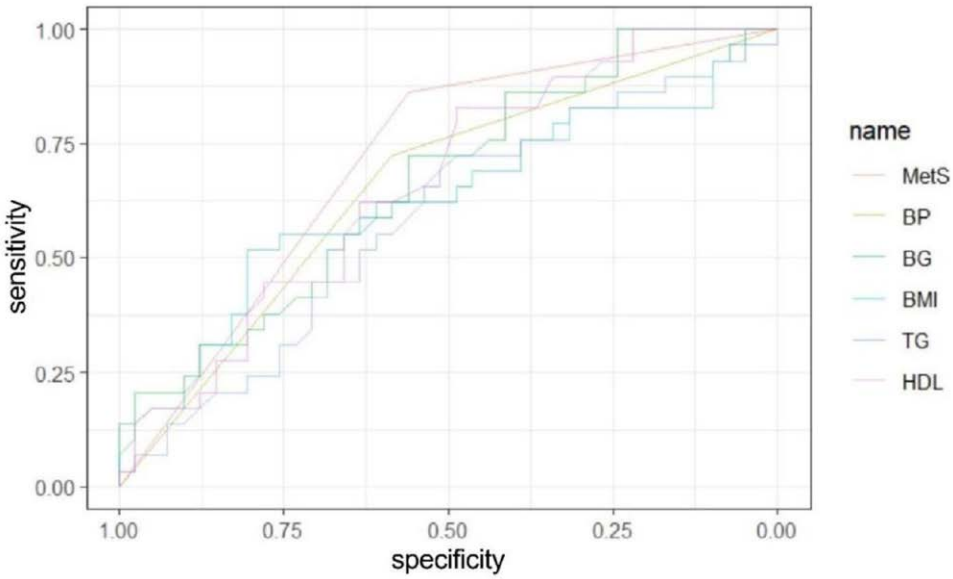

Figure 1. ROC curves and AUC representing the dynamic relationship between MetS and its components and pCR. AUC = area under the curve, MetS = metabolic syndrome, pCR = pathologic complete response, ROC = receiver operating characteristic curve.

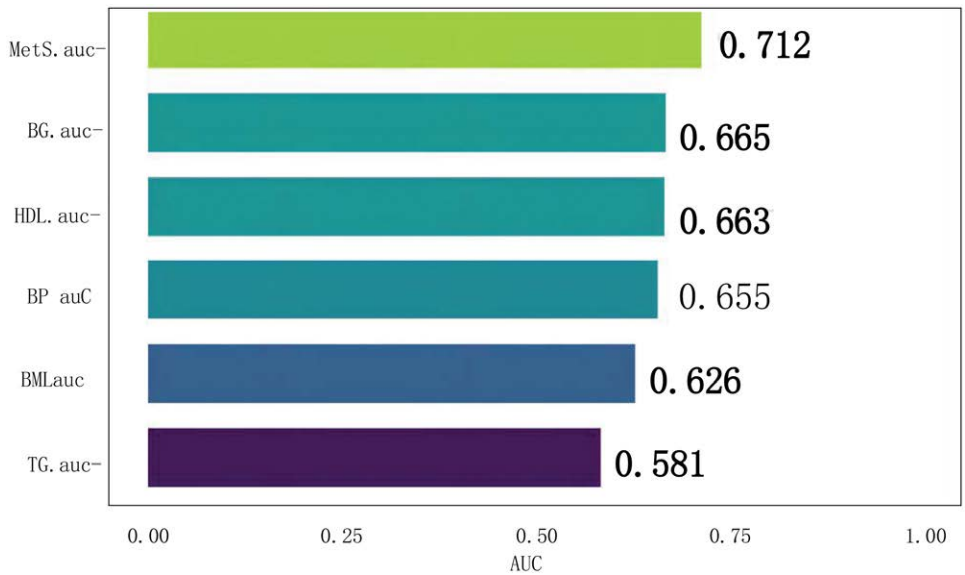

Figure 2. ROC curves and AUC representing the dynamic relationship between MetS and its components and pCR. AUC = area under the curve, MetS = metabolic syndrome, pCR = pathologic complete response, ROC = receiver operating characteristic curve.

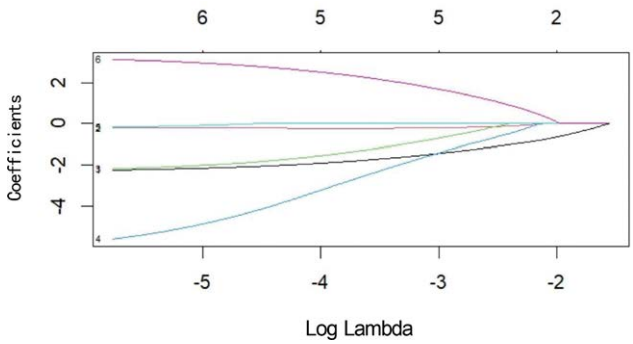

Figure 3. Optimal number of independent variables to model through lasso regression analysis.

and AUC = 0.555 for TG ≥ 1.7 mmol/L. AUC = 0.581 for BMI ≥ 25.0 kg/m^2 and AUC = 0.655 for TG ≥ 1.7 mmol/L. The AUC has a good predictive value when it is between 0.7 and 0.9. This leads to the conclusion that the presence of MetS is a good predictor of the efficacy of NACT. In this study, R Studio 4.4.1 software was further applied to perform lasso regression analyses and plot baseline tables for whether the patients achieved pCR after MetS and its components with NACT (Figs. 3 and 4, Table 3). At the optimal λ value, MetS and its components BP, blood sugar (BG), and low-density lipoprotein (HDL) were screened as the 4 correlates affecting the pCR rate ($P < .05$). These 4 factors were used to construct a column-line graph to predict the pCR rate in BC patients after NACT, and the C-index of the prediction model in this study was 0.79, suggesting that the model had good predictive ability (Fig. 5). This prediction model was internally validated

by randomly dividing the total sample size into training and validation sets in a ratio of 7:3 and plotting the ROC curves, which showed an AUC value of 0.833 for the training set and 0.815 for the validation set (Figs. 6 and 7). Calibration curves were plotted respectively (Figs. 8 and 9). DCA was produced on this basis to assess the clinical effect of the predictive model. The DCA shows that the model has a guiding value for clinical judgement (Fig. 10).

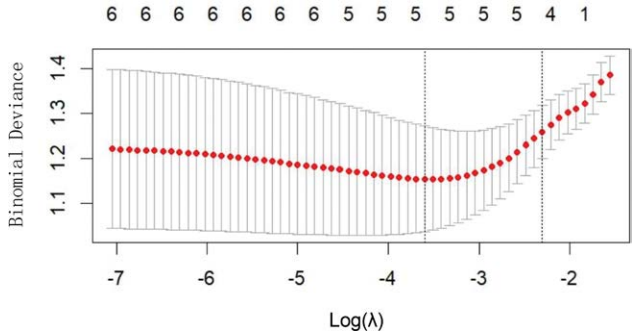

Figure 4. Optimal number of independent variables to model through lasso regression analysis.

Table 3

Univariate analysis of MetS and its components and pCR rate in breast cancer patients.

Variables	Total (n = 70)	MetS-free (n = 41)	MetS (n = 29)	*P*
MetS, n (%)				
Disease-free	43 (61)	18 (44)	25 (86)	<.001
Fall ill	27 (39)	23 (56)	4 (14)	
BP, n (%)				
Disease-free	38 (54)	17 (41)	21 (72)	.021
Fall ill	32 (46)	24 (59)	8 (28)	
BMI ($\bar{x} \pm s$)	25.45 ± 3.35	26.05 ± 3.11	24.6 ± 3.54	.081
BG, M(P25, P75)	5.31 (4.92, 5.7)	5.43 (5.03, 6.18)	5.12 (4.67, 5.51)	.020
TG, M(P25, P75)	1.58 (1.17, 2.1)	1.72 (1.23, 2.23)	1.45 (1.15, 1.86)	.252
HDL, M(P25, P75)	1.15 (1.05, 1.37)	1.11 (1, 1.27)	1.21 (1.11, 1.43)	.021

Abbreviations: BG = blood sugar, BMI = body mass index, BP = blood pressure, HDL = low-density lipoprotein, MetS = metabolic syndrome, pCR = pathologic complete response.

4. Discussion

Molecular biomarkers have always been an important basis for evaluating the prognosis of BC. In this study, we concluded that ER and PR receptor positivity was an independent factor influencing the better outcome of NACT ($P < .05$). This is consistent with the current mainstream view.[10] Also in this study, Her-2 overexpression was considered as an independent factor influencing the better efficacy of NACT ($P < .05$). This is contrary to the opinion of Tapia, Marta, Slamon[11] et al who suggested that this trait is characterized by high aggressiveness and poor prognosis. The reason for the discrepancy may be related to the relatively small sample size of this study. However, with the application of targeted drugs such as trastuzumab and cantuzumab, the prognosis of patients with Her-2 overexpression BC has been improved to a great extent.[12] Molinelli[13] et al similarly argued that tumors with low expression of Her-2 seem to be associated with a lower pCR rate in early cases, a view that is in line with the results of the present study. The high or low level of Ki-67 has long been regarded as a marker for evaluating the good or bad prognosis of BC, and high Ki-67 was significantly present in both high-grade and advanced tumors. This contradicts the view of Sana Wajid[14] et al that high Ki-67 is closely associated with a higher pCR rate after NACT. According to the data of this study, there was no statistically significant relationship between Ki-67 expression and NACT ($P > .05$), which may be related to the different cutoff values of Ki-67.

The progression of BC may depend on the associated diseases that accompany it, including type 2 diabetes, MetS and obesity.[15] Expanding on this MetS is a pathological condition in which the body undergoes metabolic disorders of proteins, fats, carbohydrates and other substances. Of these, obesity, an important component of the MetS, puts women at a significantly higher risk of developing BC, with studies showing that each 1 kg/m^2 increase in BMI increases their risk of BC by 6%, and the probability of increased risk is likely to be even greater for postmenopausal women.[16] Diabetes is another important MetS component associated with BC incidence. In a study based on 6952 long-term cancer survivors vs 1828 cancer-free control patients, it was found that the percentage of people with diabetes was lower in the long-term cancer survivors than in the control group, which just goes to show that diabetes has affected the long-term survival of patients with malignancies.[17] A study based on the analysis of the mechanism of anticancer effect of Metformin mentioned that Metformin inhibits

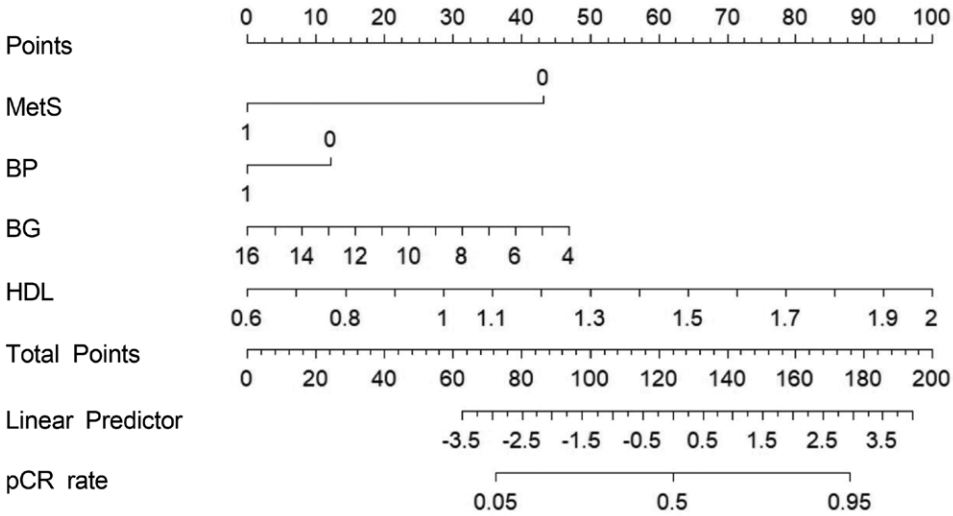

Figure 5. Column-line diagram constructed based on MetS and its 3 high-risk components vs pCR. MetS = metabolic syndrome, pCR = pathologic complete response.

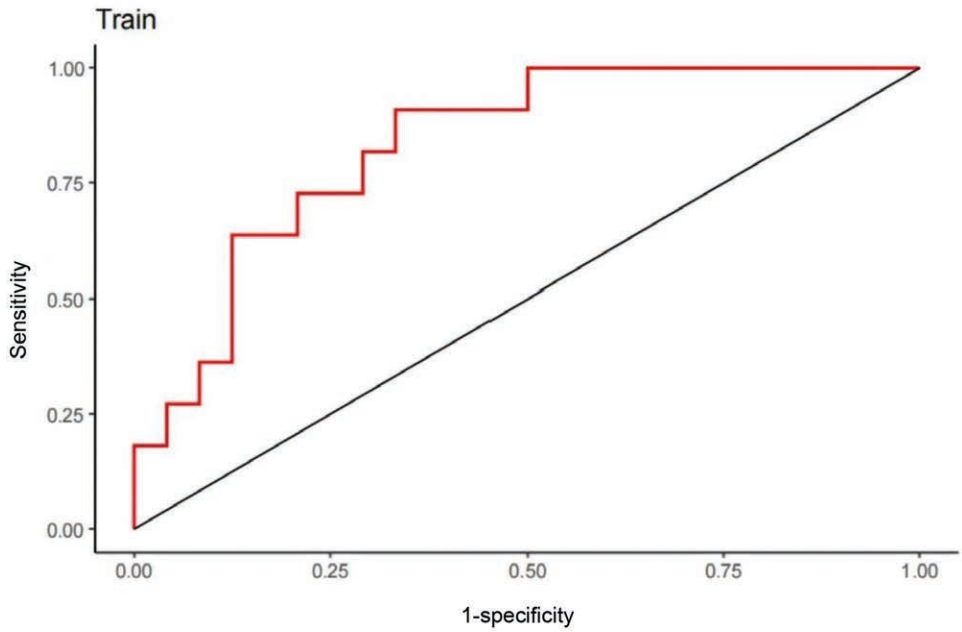

Figure 6. Internal validation of the model, divided into validation set and training set and plotted with calibration curves.

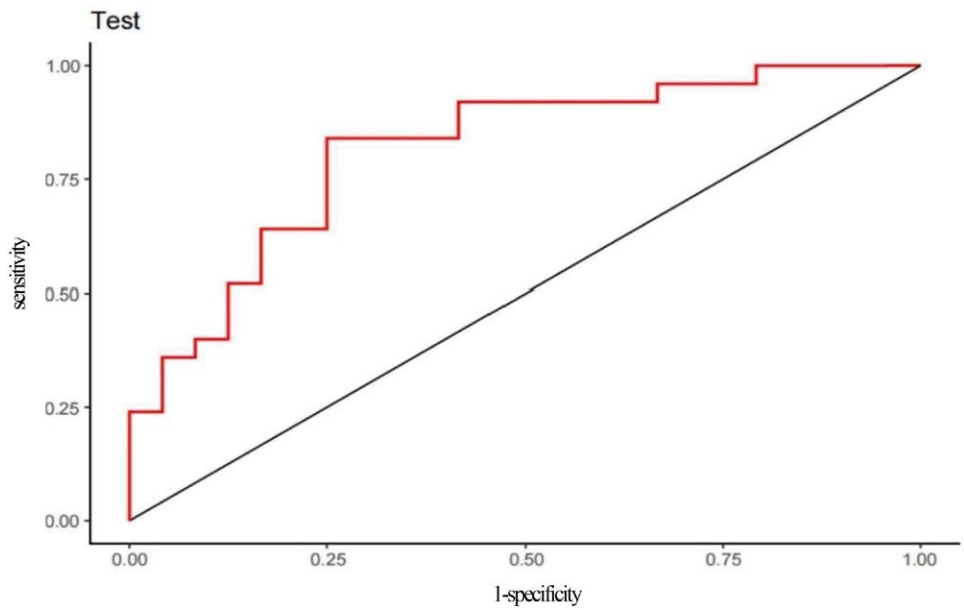

Figure 7. Internal validation of the model, divided into validation set and training set and plotted with calibration curves.

the mitochondrial efficiency in cells, so that the cellular energy deficit and redox status changes, thus achieving the dual effect of lowering sugar and anticancer. Based on clinical data, it was found that the survival period of BC and rectal cancer patients taking Metformin to control blood glucose was significantly prolonged compared with that of the control group.[18] With the improvement of economic level, people pay more attention to the dietary aspects of health, there is a prospective study from Europe, including 13,270 BC cases, the average follow-up time after diagnosis is 8.6 years, a total of 2340 deaths, of which 1475 BC deaths. The results found that surviving patients were better able to reduce the risk of developing a diabetic diet. This suggests that good blood glucose levels are strongly associated with longer survival.[19] Hypertension not only has a more direct cardiovascular impact, but also affects the prognosis of BC. Both hypertension and BC are characterized by a gradual increase in incidence with age. Timely diagnosis and treatment of hypertension may help to mitigate the cardiovascular effects of malignancy.[20] Hypercholesterolemia has been reported to affect breast tumor growth and metastasis.[21] According to the results of this study, the pCR rate after NACT was significantly correlated with whether the patient had MetS or not ($P < .05$). Taken together, the above studies and experiments are basically consistent with the results of this study.

In summary, it can be considered that BC patients with MetS have a higher probability of achieving pCR after NACT treatment than BC patients without MetS. Therefore, this study concluded that MetS can be considered as 1 of the reference indexes for predicting the efficacy of NACT. A prediction model with MetS and its high-risk components as independent variables was also

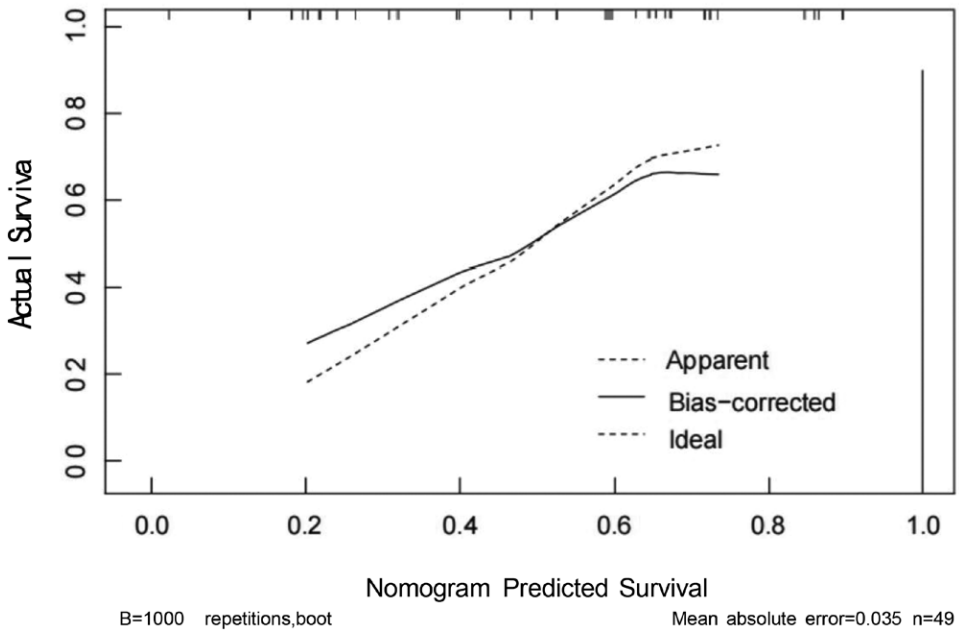

Figure 8. Internal validation of the model, divided into validation set and training set and plotted with calibration curves.

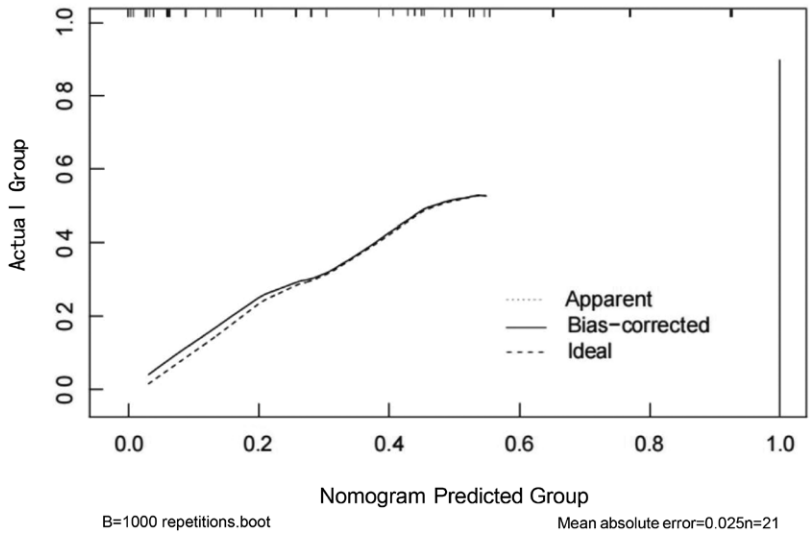

Figure 9. Internal validation of the model, divided into validation set and training set and plotted with calibration curves.

constructed, and the model was also internally validated, which, according to the calibration curve and the decision curve, showed that the model had good predictive value and clinical benefit, and could provide guidance for clinical decision-making.

However, this was a single-center retrospective study and no follow-up survival data were available. Therefore, it is necessary to conduct further long-term follow-up of the patients included in the study to obtain more supporting evidence for the correlation between MetS and NACT efficacy.

Author contributions

Conceptualization: Xiangdong Zhao, Shuaichong Ji, Kewen Lu.
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Funding acquisition: Kewen Lu, Yuexin Wang.
Investigation: Xiangdong Zhao, Chengfang Jia, Shuaichong Ji, Pei Yang, Yuexin Wang.
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Project administration: Xiangdong Zhao, Kewen Lu, Pei Yang.
Resources: Xiangdong Zhao, Kewen Lu, Pei Yang, Yuexin Wang.
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Supervision: Xiangdong Zhao, Shuaichong Ji.
Validation: Xiangdong Zhao, Chengfang Jia, Shuaichong Ji, Pei Yang.
Visualization: Xiangdong Zhao, Chengfang Jia, Pei Yang.
Writing – original draft: Xiangdong Zhao.
Writing – review & editing: Xiangdong Zhao, Yuexin Wang.

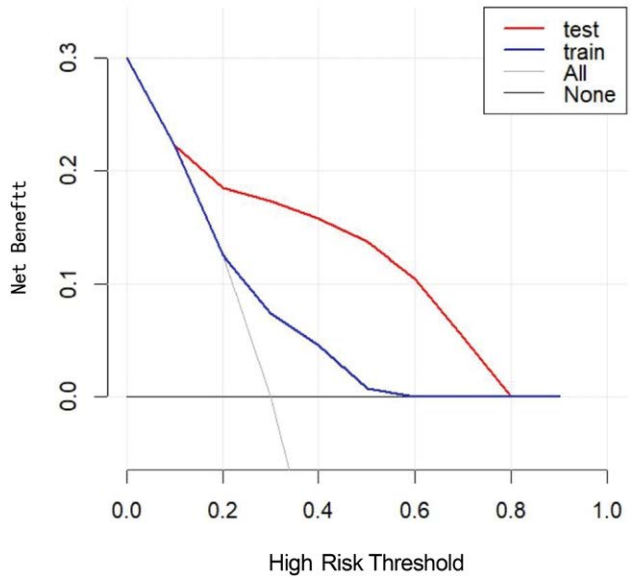

Figure 10. DCA curve of the predictive model for the effect of MetS and its components on pCR. DCA = decision curve analysis, pCR = pathologic complete response.

Correction

This article was originally published with Xiangdong Zhao spelt incorrectly as Xingdong Zhao. It has now been corrected in the online version.

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