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ABOUT COVER

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Retrospective Study

Nomogram for predicting overall survival in Chinese triple-negative breast cancer patients after surgery

Wei-Xun Lin, Yan-Na Xie, Yao-Kun Chen, Jie-Hui Cai, Juan Zou, Jie-Hua Zheng, Yi-Yuan Liu, Zhi-Yang Li, Ye-Xi Chen

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Abstract

BACKGROUND

There are few nomograms for the prognosis of Chinese patients with triple-negative breast cancer (TNBC).

AIM

To construct and validate a nomogram for overall survival (OS) of Chinese TNBC patients after surgery.

METHODS

This study used the data of SEER*stat 8.3.5 and selected Chinese patients with TNBC operated on between 2010 and 2015. Univariate and multivariate Cox proportional hazard regression models were used. The identified variables were integrated to form a predictive nomogram and risk stratification model; it was assessed with C-indexes and calibration curves.

RESULTS

The median and maximal OS of the 336 patients was 39 and 83 mo, respectively. The multivariate analysis showed that age ($P = 0.043$), marital status ($P = 0.040$), tumor localization ($P = 0.030$), grade ($P = 0.035$), T classification ($P = 0.012$), and N classification ($P = 0.002$) were independent prognostic factors. The six variables were combined to construct a 1-, 3- and 5-year OS nomogram. The C-indexes of the nomogram to predict OS were 0.766 and compared to the seventh edition staging system, which was higher (0.766 vs 0.707, $P < 0.001$). In order to categorize patients into different prognostic groups, a risk stratification model was created. There was a significant difference between the Kaplan-Meier curves of the entire

cohort and each disease stage according to the nomogram.

CONCLUSION

The nomogram provided prognostic superiority over the traditional tumor, node and metastasis system. It could help clinicians make individual OS or risk predictions for Chinese TNBC patients after surgery.

Key Words: Triple-negative breast cancer; Chinese; nomogram; Risk stratification; Overall survival

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Core tip: This study aimed to construct and validate a nomogram for overall survival (OS) of triple-negative breast cancer (TNBC) patients after surgery. The data from SEER*stat 8.3.5 of selected Chinese surgical patients with TNBC between 2010 and 2015 were used. The multivariate analysis showed that age ($P = 0.043$), marital status ($P = 0.040$), tumor localization ($P = 0.030$), grade ($P = 0.035$), T classification ($P = 0.012$), and N classification ($P = 0.002$) were independent prognostic factors. A risk stratification model was generated. The C-indexes of the nomogram to predict OS were 0.766 and compared to the seventh edition tumor, node, metastasis (TNM) staging system, which was higher (0.766 vs 0.707, $P < 0.001$). The nomogram provided a clear prognostic superiority over the traditional TNM system.

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INTRODUCTION

Breast cancer (BC) is the most common malignancy diagnosed in women worldwide, with 2 088 849 new cases and 626 679 deaths in 2018[1]. BC has several risk factors, including genetic causes, aging, reproductive history, hormone exposure, lifestyle factors, medical history, and radiation exposure[2-4]. The management of BC is multidisciplinary[2,5,6]. Endocrine therapy can be used to prevent the recurrence of hormone (estrogen and/or progesterone) receptor-positive BC, while anti-HER2 therapies can be used to improve the prognosis of HER2-positive BC[2]. In the USA, therefore, the 5-year survival rate for women with localized BC is 99%, 85% for women with regional spread, and 27% for women with distant metastases[2,4]. Factors affecting prognosis include tumor and disease characteristics, age, response to therapy, race, ethnicity, and body mass[2]. Triple-negative BC (TNBC) is characterized by the absence of hormone receptor expression and HER2 overexpression[7-9]. TNBC represents 15%-20% of all BCs and has more aggressive biology, earlier onset of metastatic disease, visceral metastases, rapidly progressive disease, inefficacy of endocrine therapy, short response duration to available therapies, and inferior survival outcomes[10-12]. The survival of patients with TNBC is influenced by age at diagnosis, tumor stage, positive lymph node ratio, and Ki-67[13]. Ovcaricek *et al*[14] showed that age and nodal status are prognostic factors in such patients, while Pistelli *et al*[15] showed that tumor size and lymphovascular invasion are prognostic factors for TNBC. Because of the malignant behavior of TNBC and to achieve a better prognostic assessment, stratifying patients with TNBC based on their individual characteristics is important. Nomograms are useful and convenient tools for cancer patients to quantify and predict risk and prognosis[16-18]. Many prognostication nomograms have been developed and validated for BC patients based on traditional clinicopathological features[19,20]. Hwang *et al*[19] limited their nomogram to pathological complete response after neoadjuvant chemotherapy, while Luo *et al*[20] included radiomics in their nomogram, which might not be readily available in all hospitals. Most models were developed using Caucasian and not Asian patients. A SEER-based study showed that Chinese women had better 10-year survival than Caucasians had[21]; similar results were observed in Japanese women[22]. A study suggested that the prognosis of TNBC was similar between Asians and Caucasians, but the sample size was small[23]. There are currently few nomograms for Chinese patients with TNBC. Yang *et al*[24] and Shi *et al*[25] developed such a nomogram, but their predictive value was fair at best. Wang *et al*[26] developed a nomogram specifically for TNBC patients with *de novo* metastasis. Thus, the present study aimed to establish and validate a nomogram for TNBC in Chinese patients after surgery. This tool could help improve the management of TNBC in Chinese women.

MATERIALS AND METHODS

Study design and patient selection

This study used the data from SEER*stat 8.3.5 and patients undergoing TNBC surgery between 2010 and 2015 were included. The inclusion conditions were (1) Chinese patients with histologically confirmed primary TNBC; (2) > 18 years of age at diagnosis; and (3) underwent primary tumor resection. The exclusion criteria were: (1) Male BC; (2) missing follow-up information; (3) missing data regarding tumor stage, histological grade, tumor size, therapy, or marital status; or (4) distant metastasis.

Statistical analysis

Categorical data were presented as n (%) and analyzed using the χ^2 test. Univariate comparisons of survival data were performed using the Kaplan–Meier method and compared using the log-rank test and Cox analyses. Based on the univariable Cox analyses ($P < 0.10$) and considering clinically relevant factors, multivariate analysis using the Cox risk regression model with backward elimination was performed. Using the results of the multivariate analysis, variables with $P = 0.05$ were chosen for development of the nomograms.

To create the nomogram, we used 1-, 3- and 5-year OS. We calculated the C-indexes and generated calibration plots using 1000 bootstrap resamples to assess the nomogram's predictive accuracy. Using the average score of each patient in the nomogram, the risk stratification model was developed to group the patients into two prognostic groups. The analyses were all performed with R (<http://www.r-project.org>) and Empower (R, v 3.6.3) (www.empowerstats.com, XY Solutions, Inc., Boston, MA, USA). Two-tailed $P < 0.05$ was considered statistically significant. The details of the nomogram and recursive partitioning analysis are presented as an appendix.

RESULTS

Patient characteristics

Finally, 336 patients were identified from the SEER database according to the screening (Figure 1). The median age was 57 years (range: 28–100 years). The median follow-up was 39 mo. The 1-, 3- and 5-year survival rates were 94.0%, 53.6% and 29.8%, respectively. Tumors ≥ 3 cm accounted for 16.4% of the cases. Among the 336 patients, 101 (30.1%) patients were unmarried, and 171 (50.9%) had left-sided cancer. Demographics, clinicopathological characteristics, and therapy are summarized in Table 1.

Identification of independent prognostic factors

The univariable Cox regression analyses demonstrated that age at diagnosis, marital status, laterality, histological grade, T classification, N classification, and radiotherapy were associated with OS. Unmarried status ($P = 0.016$) and right-side BC ($P = 0.003$) were associated with poorer survival (Supplementary Figure 1). These factors were brought into the multivariate Cox regression analysis. Age at diagnosis ($P = 0.043$), marital status ($P = 0.040$), tumor localization ($P = 0.030$), grade ($P = 0.035$), T classification ($P = 0.012$), and N classification ($P = 0.002$) were used to develop the nomogram.

Constructing and validating the nomogram

The Nomogram was composed of six independent factors (Figure 2). We gave a score for each category on the point scale axis (Supplementary Table 1). By adding up each score and projecting the total score onto the lowest scale, an overall score was calculated to estimate each patient's OS at 1, 3 and 5 years.

The C-index of the nomogram was higher than the C-index of the 7th version of the American Joint Committee on Cancer tumor, node and metastasis (AJCC TNM) staging system (0.766 vs 0.707, $P < 0.01$), indicating that predictive accuracy of the nomogram was acceptable. Calibration plots of the nomogram (Figure 3) demonstrated that the predicted OS closely matched the actual observations. Decision curve analysis is an analysis of net benefits that calculates the true-positive rate in relation to the weighted false-positive rate for different thresholds of risk that a clinician or patient may accept. This analysis was used to evaluate the 5-year OS of TNBC patients. All models had higher net returns than the "treat all" strategy (Figure 4). In most of the decision threshold probabilities, the nomogram decision model has a higher net benefit than the TNM phase model.

Risk stratification system

The results supported the predictive efficacy of the nomogram for OS. Therefore, we calculated the total score based on the nomogram prediction score. Patients were divided into two groups based on median: low risk (total score < 101.028) and high risk (total score ≥ 101.028). In the entire cohort, the 5-year OS rates of the patients with low and high risk were 31.9% and 27.8%, respectively (Figure 5). To validate the supplementary role of the risk stratification system to the 7th version of the AJCC-TNM staging system, we stratified the training cohort according to the TNM stage. Therefore, no significant

Table 1 Demographics and clinicopathological characteristics of triple-negative breast cancer patients

Characteristics	<i>n</i> = 336
Age at diagnosis, years, median (range)	57 (28-100)
Marital status, <i>n</i> (%)	
Unmarried	101 (30.1)
Married	235 (69.9)
Laterality, <i>n</i> (%)	
Left	171 (50.9)
Right	165 (49.1)
Tumor size, cm, <i>n</i> (%)	
< 3	281 (83.6)
≥ 3	55 (16.4)
Grade, <i>n</i> (%)	
Well-differentiated (I-II)	103 (30.7)
Poorly differentiated (III)	233 (69.3)
Stage, <i>n</i> (%)	
I	146 (43.5)
II	160 (47.6)
III	30 (8.9)
T classification, <i>n</i> (%)	
T1	169 (50.3)
T2	143 (42.6)
T3	18 (5.4)
T4	6 (1.8)
N classification, <i>n</i> (%)	
N0	244 (72.6)
N1	67 (19.9)
N2	17 (5.1)
N3	8 (2.4)
Radiotherapy, <i>n</i> (%)	
None	190 (56.6)
Yes	146 (43.4)
Chemotherapy, <i>n</i> (%)	
None	109 (32.4)
Yes	227 (67.56)

distinction was found for stage III ($P = 0.21$). Moreover, within each TNM stage, there were significant differences between Kaplan–Meier curves in the survival predicted by the row plots (Figure 5).

DISCUSSION

The AJCC-TNM staging classification is the most widely used system for risk stratification and the selection of the treatment strategy for cancer patients[27,28]. However, this classical system does not accurately identify survival differences among cancer subtypes[29]. The TNM staging system ignores many factors that were confirmed to be highly associated with OS. At present, there are few nomograms for the prognosis of Chinese patients with TNBC. The aim of this study was to construct and validate a

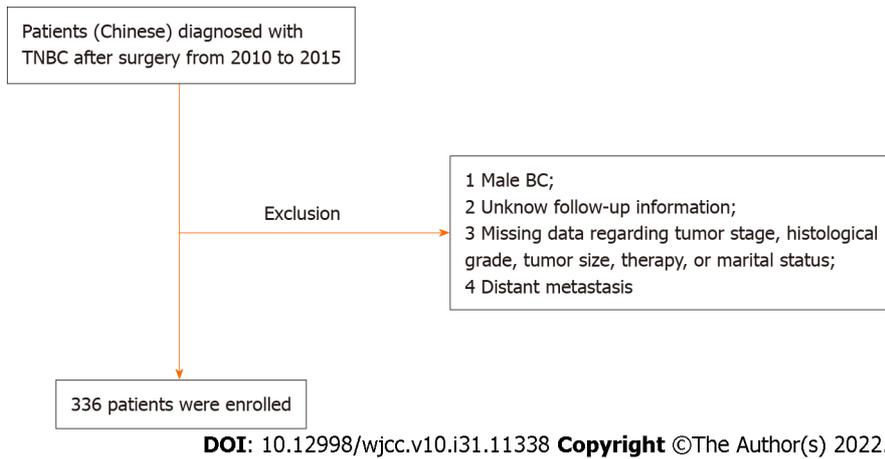


Figure 1 Patient flowchart. BC: Breast cancer; TNBC: Triple-negative breast cancer.

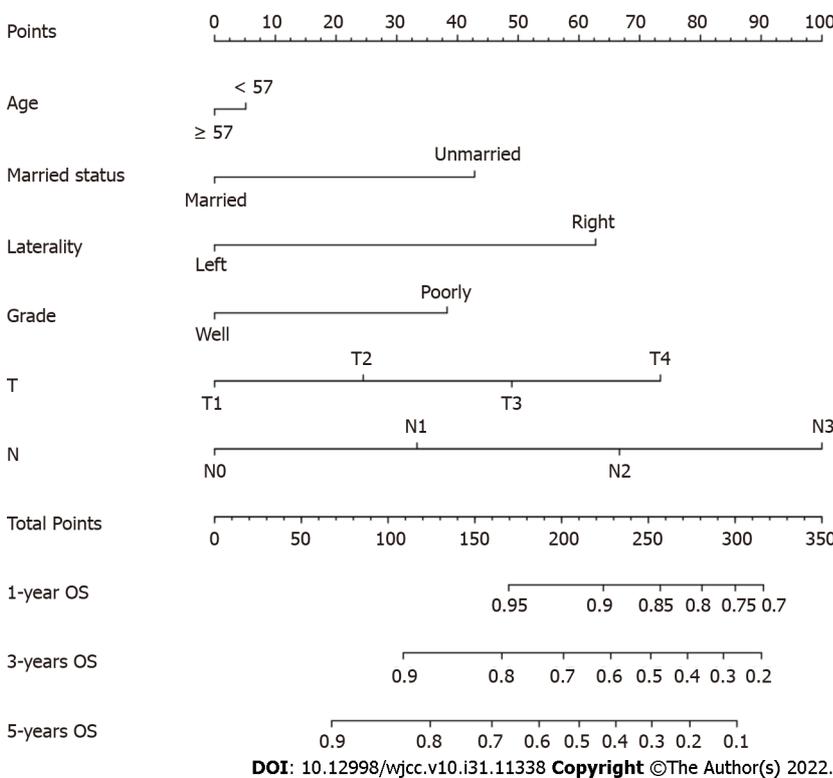
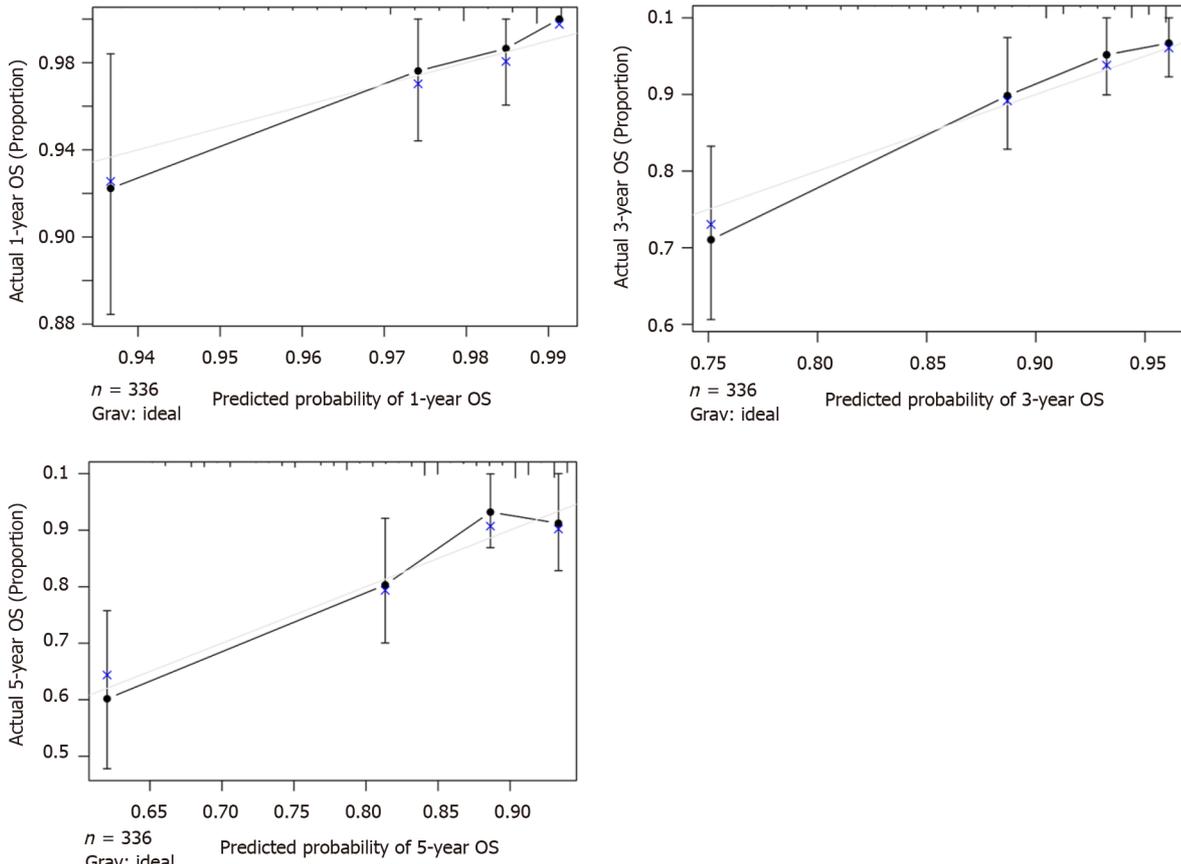


Figure 2 Nomogram predicting 1-, 3- and 5-year overall survival for Chinese triple-negative breast cancer patients after surgery. OS: Overall survival.

nomogram for OS of Chinese TNBC patients after surgery. The results suggest that the nomogram developed in this study has superior prognostic value than the traditional TNM system has. The nomogram could help clinicians make individual survival or risk prediction for Chinese TNBC patients after surgery and give necessary treatment recommendations.

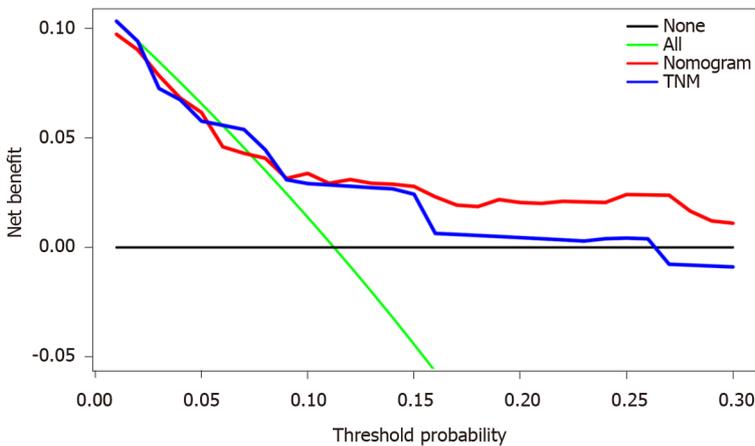
Few independent studies have been conducted on nomogram survival to predict postoperative survival in Chinese TNBC patients; the sample size was small and the prognostic factors were insufficient[24,25,29]. Thus, the present study used the survival data of the SEER database. The SEER registry, the largest population-based cancer patient database in the USA, covers about 26% of patients diagnosed with cancer[30,31]. Patient data from the latest version of SEER published in 2015 (covering 18 registries, 1973–2015) were collected using SEER*Stat 8.3.5 under strict inclusion and exclusion criteria.

Four independent prognostic factors were identified through univariate and multivariate Cox regression analyses, including age at diagnosis, marital status, laterality, histologic grade, T classification, and N classification. These variables were finally incorporated into the nomogram. The



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Figure 3 Calibration curves predicting 1-, 3- and 5-year overall survival. OS: Overall survival.

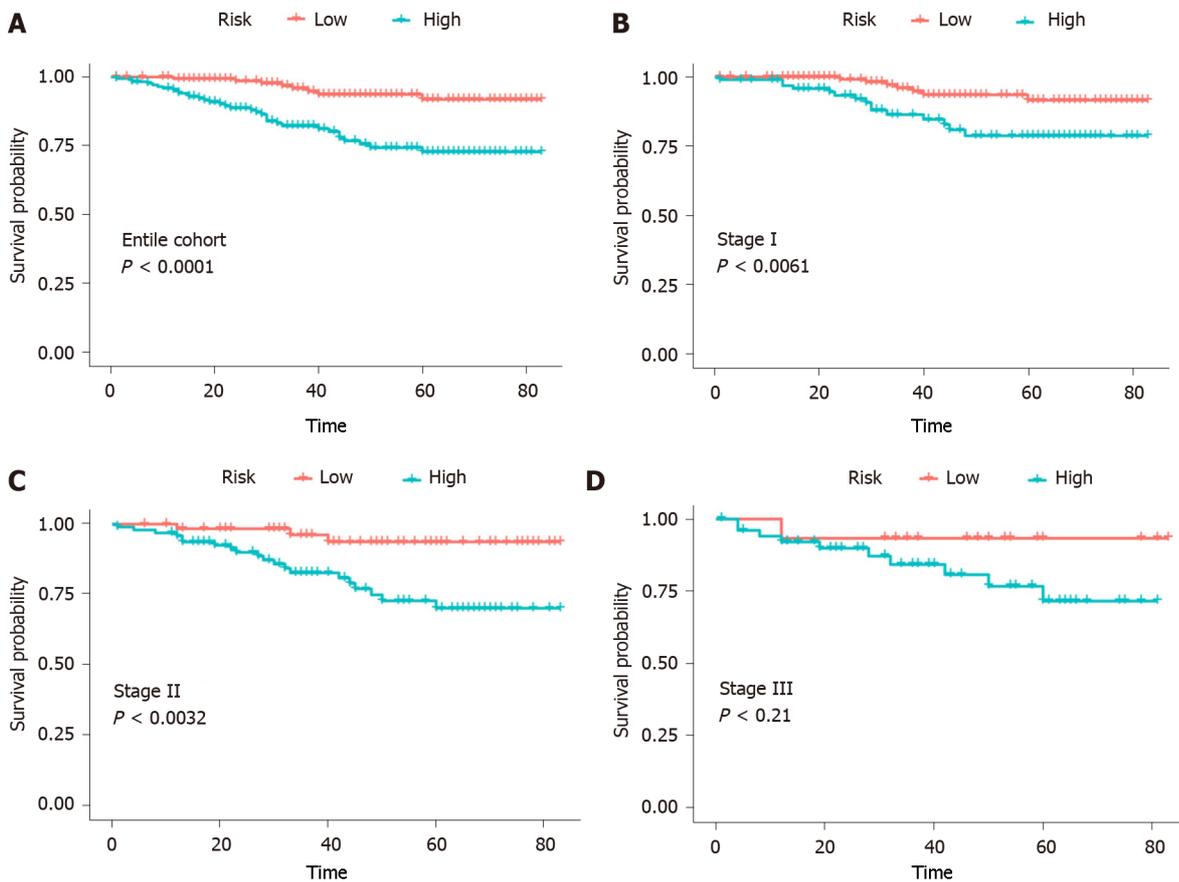


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Figure 4 Analysis of the decision curve showing the performance comparison. On the black line, it is assumed that no patient should take the necessary measures, and on the green line, it is assumed that all patients should. By adding benefits points and subtracting harm points, the y axis represents the net benefit. Our results indicated that the nomogram (red line) provided a higher net benefit than the tumor, node and metastasis staging model (blue line), based on threshold probabilities. TNM: Tumor, node, metastasis.

findings were consistent with previous studies on survival risk factors for TNBC patients but not identical. The nomogram by Jiang *et al*[29] included age, tumor grade, and TNM stage. Yang *et al*[24] included stromal tumor-infiltrating lymphocytes, tumor size, nodal status, and Ki-67 index. Finally, Shi *et al*[25] included albumin-to-globulin ratio, neutrophil-to-lymphocyte ratio, positive lymph nodes, and tumor size.

The nomogram developed here showed that N classification made the largest contribution to prognosis. The N3 stage was highly associated with poor prognosis in Chinese TNBC patients. A



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Figure 5 Risk stratification of the nomogram. A: Kaplan–Meier curve for overall survival in the entire cohort; B: Stage I; C: Stage II; D: Stage III triple-negative breast cancer patients after surgery. TNM: Tumor, node, metastasis.

previous study demonstrated that among lymph node-positive TNBCs, the lymph node ratio appeared to be a stronger predictor of mortality than pathological lymph nodes stage (hazard ratio: 0.80 for pN3 vs pN1, and 3.05 for > 0.65 vs < 0.21 lymph node ratio)[13].

This study also found that the survival of Chinese TNBC patients was associated with tumor laterality. Left-sided cancer had better OS than right-sided cancer. There is a slight excess of BC in the left breast compared with the right[32,33], but previous studies have been hampered by small numbers or limited geographic or demographic populations. Since the laterality difference is small, it has been difficult to appreciate the clinical or biological characteristics associated with left BC predominance[34]. Several studies have linked marital status to cancer outcomes in soft tissue sarcoma and small intestinal adenocarcinoma rectal cancer[35,36]. The present study also had clear survival discrimination in patients with different marital statuses, probably caused by reproductive factors[2].

The necessary identification and calibration evaluations are necessary to ensure the validity of nomograms, to maximize their generalizability and avoid overfitting. Discrimination is usually evaluated with the C-index, and calibration is assessed by comparing the agreement between predicting and actual patient survival. The results suggested that the nomogram developed in this study had better predictive and discriminative ability compared with traditional staging systems. Decision curves analysis was performed to examine the clinical net benefit in Chinese TNBC patients' prognosis when using the nomogram. The results showed that model improved the clinical net benefit of all threshold probabilities[37,38].

Finally, a system was constructed to classify the patients into two risk subgroups based on the predicted total scores. When we applied the risk stratification system to evaluate patients at the same stage, we could discriminate OS in stages I and II but not in stage III patients. One important reason might be the small sample size. Thus, the nomogram risk stratification system is an accurate and reliable prognostic model supported by all results. It is beneficial for clinicians to identify high-risk patients and conduct necessary adjunctive therapy.

There were some limitations to this study. First, this was a retrospective study based on the SEER database, which has its limitations[39]. There was a possible selection bias regarding the variables included in the nomogram. The SEER database does not contain information on modern gene-array technology or some important molecular factors, such as programmed death ligand 1 expression or microsatellite status, which have been associated with OS in colon cancer[40]. Subsequent analysis

might improve the study design in the future. Finally, the sample of Chinese patients with TNBC was small in the SEER database. In addition, they were individuals of Chinese descent but living in the USA. Therefore, they do not completely represent the Chinese population living in China. Future studies should aim at validating the results in China.

CONCLUSION

A novel nomogram for predicting OS after surgery in Chinese TNBC patients was developed and validated. The included factors are all easy to obtain in the clinical setting, and the prognostic model is convenient to use. This nomogram provides a clear prognostic superiority over the AJCC-TNM 7 system. It is the first model that is suitable for risk stratification in long-term survival for Chinese TNBC patients.

ARTICLE HIGHLIGHTS

Research background

Triple-negative breast cancer (TNBC) represents 15%–20% of all BCs and has more aggressive biology, earlier onset of metastatic disease, visceral metastases, rapidly progressive disease, inefficacy of endocrine therapy, short response duration to available therapies, and inferior survival outcomes. Nomograms are useful and convenient tools for cancer patients to quantify and predict risk and prognosis. At present, there are few nomograms for Chinese TNBC patients. Thus, the present study aimed to establish and validate a nomogram for TNBC in Chinese patients after surgery. This tool could help improve the management of TNBC in Chinese women.

Research motivation

To explore a nomogram for predicting overall survival in Chinese TNBC patients after surgery.

Research objectives

To construct and validate a nomogram for the overall survival (OS) of Chinese TNBC patients after surgery.

Research methods

This study used the data of SEER*stat 8.3.5 and selected Chinese patients with TNBC operated upon between 2010 and 2015. Univariate and multivariate Cox proportional hazard regression models were used. A predictive nomogram and risk stratification model was constructed by integrating the identified variables; it was assessed with C-indexes and calibration curves.

Research results

The median and maximal OS of the 336 patients was 39 and 83 mo, respectively. The multivariate analysis showed that age ($P = 0.043$), marital status ($P = 0.040$), tumor localization ($P = 0.030$), grade ($P = 0.035$), T classification ($P = 0.012$), and N classification ($P = 0.002$) were independent prognostic factors. The six variables were combined to construct a 1-, 3- and 5-year OS nomogram. The C-indexes of the nomogram to predict OS were 0.766, which was higher than that of the seventh edition tumor, node, metastasis (TNM) staging system (0.766 *vs* 0.707, $P < 0.001$). Using the average score of each patient in the nomogram, the risk stratification model was developed to group the patients into two prognostic groups. There was a significant difference between the Kaplan–Meier curves of the entire cohort and each disease stage according to the nomogram. Future studies should aim at validating the results in China.

Research conclusions

A novel nomogram for predicting OS after surgery in Chinese TNBC patients was developed and validated. The included factors are all easy to obtain in the clinical setting, and the prognostic model is convenient to use. This nomogram provides a clear prognostic superiority over the TNM system. It is the first model suitable for risk stratification in long-term survival for Chinese TNBC patients.

Research perspectives

The sample of Chinese patients with TNBC was small in the SEER database. In addition, they were individuals of Chinese descent but living in the USA. Therefore, they do not completely represent the Chinese population living in China. Future studies should aim at validating the results in China.

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FOOTNOTES

Author contributions: Lin WL, Xie YN, Chen YX, Li ZY, Liu YY, and Cai JH designed the study and conceived the project; Zou J, Zheng JH, Chen YK, and Xie YN performed the experiments and analyzed the data; Lin WX and Xie YN drafted the manuscript; All authors have read and approved the manuscript.

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