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Research Article

A NOMOGRAM FOR PREDICTING SURVIVAL OUTCOMES IN LOCALLY ADVANCED BREAST CANCER

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A R T I C L E I N F O

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A B S T R A C T

Background: To construct and validate a nomogram to predict overall survival of patients with locally advanced breast cancer (LABC) using parameters that are measured during routine clinical management.

Patients and methods: Data from 531 patients treated for LABC at a single institution Tata Memorial Hospital, Mumbai from Jan 2008 to Dec 2008 were analyzed. The eligible patients were randomized 4:1 and divided into a training set (nomogram construction) and a validation set (nomogram validation). We used bootstrap resampling for the internal validation and we tested the nomogram on an independent validation set of patients for the external validation.

Results: The nomogram were based on a Cox proportional hazards regression model. Covariates for the overall survival model included tumor grade, molecular subtype, presence of lymphovascular invasion, presence of extensive intraductal component and pathological lymph nodal status. The nomogram was found to have a c-index of 0.7196 for predicting the five year OS. The calibration curve suggested that the model was well calibrated for all predictors. The nomogram for LABC based on these variables had good discrimination in training as well in validation set (AUC, 0.743 and 0.753).

Conclusion: A nomogram based on parameters that are measured on a routine basis was developed. The nomogram can be used to predict five-year OS with reasonable accuracy. This information will be useful for estimating prognosis and in guiding treatment selection.

INTRODUCTION

According to GLOBOCAN 2012 estimates, breast cancer is the second most common cancer in the world, and is the most frequent cancer among women with an estimated 1.67 million new cancer cases diagnosed in 2012 (25 % of all cancers). It is a rising menace in both developing and developed countries.[1] Locally advanced breast cancer (LABC) is associated with dire prognosis despite progress in multimodal treatment.[2] Women with advanced breast cancer constitute a heterogeneous group of patients with tumors that show variable biological behavior, response to therapy, and prognosis.[3] Prognostic factors are essential in order to predict the risk of disease recurrence and to provide increasingly more individualized treatment to patients. The well recognized important prognostic factors are lymph node status at diagnosis, tumor grade and the status of hormone receptors and human epidermal growth factor receptor2 (HER2).[4,5]

Advancement of the disease ultimately affects the overall prognosis and increases the cost of treatment. Clinical management of breast cancer relies on the availability of robust clinical and pathologic, prognostic and predictive factors to support the decision making of clinicians and patients. Accurate predictions of survival time are important for providing valuable prognostic information for patients and guiding oncologists for adjuvant therapy and stratifying patients for future clinical trials.

Nomogram is a predictive tool that creates a simple graphic representation of a statistical predictive model that generates a numeric probability of a clinical event.[6] It can provide individualized prognostic information based on the prognostic factors and be more accurate than the conventional staging systems for predicting prognosis in some cancers.[7,8] Unfortunately, no single study evaluating the role of nomogram for survival prediction in LABC patients is available. The purpose of this study was to develop and validate a nomogram that can accurately predict an individual patient's overall survival (OS) using available information for surgically managed LABC patients.

MATERIALS AND METHODS

Patient selection and data processing

Relevant clinical information (age, menopausal status, tumor size and treatment), Axillary lymph node status and surgical histopathological information were recorded from 531 patients who received Neoadjuvant chemotherapy (NACT) as

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well as standard surgery at Tata Memorial Hospital, Mumbai (TMH) between January 1, 2008 and December 31, 2008.
The eligibility criteria included: 1) Patients with histologically proven LABC (AJCC TNM 2010, 7th edition, 2010), and 2) received NACT as well as standard surgery. Patients with missing data were excluded. The eligible patients were randomized 4:1 and divided into a training set (nomogram construction) and a validation set (nomogram validation). The study had the approval of the research ethics committee of the hospital.

Construction and validation of the nomogram

Statistical analyses to identify independent prognostic factors were conducted with SPSS 21.0 for Windows (SPSS, Chicago, IL, USA). Considering the importance of independent validation, we adopted a data-splitting method using uniform function in SPSS to randomly assign 80% of the patients to the training set (nomogram construction) and 20% to the validation set (nomogram validation).[9] Overall survival (OS) was calculated from the date of diagnosis. The OS curves were generated using the Kaplan–Meier method and were compared using the log-rank test.

Covariates achieving significance at a level of $P < 0.05$ were entered into the Cox regression model for multivariate analyses. Based on the results from multivariate analysis, a nomogram was formulated using STATA version 12.0 with the survival and Nomocox package.[9-12]

The derived scores from nomogram were divided into two groups based on the median cutoff value. The discrimination ability of the nomogram was internally validated using estimation of bootstrap-adjusted c-index with 1000 bootstrap resamples.[13] The value of the c-index ranged from 0.5 to 1.0, which indicates random chance to a perfect ability to correctly discriminate between the outcome and model.[9] The internal validation was also checked by area under the receiver operating characteristic (AUC). The external validation of the nomogram was performed by calculating the AUC in an independent validation set. In addition to survival probability, in both training and the validation sets a score for each patient was calculated from the nomogram. Patients were then grouped into 2 categories with respect to their nomogram-based scores.

RESULTS

Demograhic and clinicopathologic characteristics of patients

A total of 531 patients with LABC stage who had undergone at least surgery were eligible for final analysis. The 5 year OS of the cohort was 69.1%. Of the 531 patients, 424 (80%) were assigned to the training set, and 107 (20%) to the validation set. In the training set, the median age was 48 years (range, 24–89 years). At the end of follow-up (December 31, 2014), among these 424 patients 121 had died, and 303 were censored. The median follow-up period was 68 months (range, 2–84 months). The demographic and clinicopathologic features of patients in the training set and validation set are summarized in Table 1.

Table 1 Demographic and clinicopathologic characteristics of LABC in the training set and internal validation set

Variables	Training Group (n = 424)	Overall Survival		Validation Group (n = 107)
	No. (%)	5-yr	P value	No. (%)
Demographic Variables				
Age at diagnosis (years)				
Median, Range	48, 24-89			49, 26-82
Menopausal status				
Premenopausal	200 (47.2)	0.709	0.464	49 (45.8)
Postmenopausal	224 (52.8)	0.674		58 (54.2)
Education status				
Illiterate	101 (23.8)	0.599	0.033	31 (29.0)
Literate	323 (76.2)	0.719		76 (71.0)
Comorbidities				
Present	88 (20.8)	0.621	0.100	21 (19.6)
Absent	336 (79.2)	0.710		86 (80.4)
Clinico-pathological variables				
Tumor Location				
Outer	154 (36.3)	0.696	0.921	44 (41.1)
Inner + Central	270 (63.7)	0.688		63 (58.9)
Histological type				
Ductal	409 (96.5)	0.688	0.654	100 (93.5)
Lobular	3 (0.7)	0.667		1 (0.9)
Other	12 (2.8)	0.800		6 (5.6)
Tumor grade				
Low grade	56 (13.2)	0.868	0.004	16 (15.0)
High grade	368 (86.8)	0.663		91 (85.0)
Molecular subtype				
Luminal type	201 (47.4)	0.747	0.028	40 (37.4)
HER-2 enriched	36 (8.5)	0.665		18 (16.8)
Triple Negative	187 (44.1)	0.637		49 (45.8)
Lymphovascular invasion				
Negative	314 (74.1)	0.755	<0.001	86 (80.4)
Positive	110 (25.9)	0.507		21 (19.6)
Extensive Intraductal component				
Negative	384 (90.6)	0.719	<0.001	92 (86.0)
Positive	40 (9.4)	0.417		15 (14.0)
No. of positive lymph nodes (Pathological)				
0	135 (31.8)	0.873	<0.001	37 (34.6)
1-3	130 (30.7)	0.698		31 (29.0)
> 3	159 (37.5)	0.528		39 (36.4)

Table 2 Multivariate analysis of 5-year outcome: the final predictors for developing the nomogram

Variable	Cox PH Regression	
	HR (95% CI)	P value
Age at diagnosis (years) †		0.98
Tumor grade		
low grade	Ref	
High grade	2.03 (0.93-4.42)	0.07
Molecular subtype		
Luminal type	Ref	
Her-2 over expressed	1.39 (0.71-2.70)	0.32
Triple negative	2.28 (1.54-3.39)	<0.001
LVI		
Negative	Ref	
Positive	1.54 (1.03-2.29)	0.03
EIC		
Negative	Ref	
Positive	1.85 (1.13-3.01)	0.01
Number of positive lymph nodes		
0	Ref	
1-3	3.07 (1.68-5.61)	<0.001
≥ 4	4.90 (2.71-8.85)	<0.001

Abbreviations: HR, hazard ratio; CI, confidence interval; PH, proportional hazards; Ref, reference category; LVI, lymphovascular invasion; EIC, extensive intraductal component.
* Statistically significant with p < 0.05. † Age at diagnosis (years) was analyzed as a continuous variable.

Independent prognostic factors in the training set

The data from the training set were used to identify prognostic factors and build the model. Variables considered significant in the univariate analyses were entered in the Cox multivariate analysis. A total of 5 variables, including tumor grade, molecular subtype, presence of lymphovascular invasion, presence of extensive intraductal component and pathological lymph nodal status were found to be independent predictors of survival in the multivariate Cox regression model and were incorporated in the nomogram (Table 2).

Prognostic nomogram for OS prediction

Using the data of patients in the training set, a nomogram was constructed for OS prediction (Fig. 1). Longer lines indicate greater prognostic impact of specific variables, and larger points in the nomogram indicate shorter OS. The Pathological Lymph nodes had the greatest impact on OS, which was followed by the Molecular subtype, EIC, tumor grade and LVI. Each subtype within the above variables was assigned a score on the point scale. By adding up the total score and locating it on the total point scale, we could easily draw a straight line down to determine the estimated probability of survival at each time point. The total scores ranged from 5.5 to 23.5. By dividing the range into two groups based on median cutoff value, we determined two subgroups of patients: Group I (score ≤14) and Group II (score ≥ 14.5). The 5 year OS rates of the two subgroups with nomogram scores of 0–14 and ≥14.5 in training set were 84.1 and 53.1% respectively (chi-square =45.59; p <0.00). Similarly in validation set the 5yr OS in the two groups were found to be 83.1 and 43.7 % respectively (chi-square =12.12; p <0.00). In comparison, the five year survival rate for the patients in training set and validation set by Kaplan Meir was found to be 69.1% and 66.1% respectively.

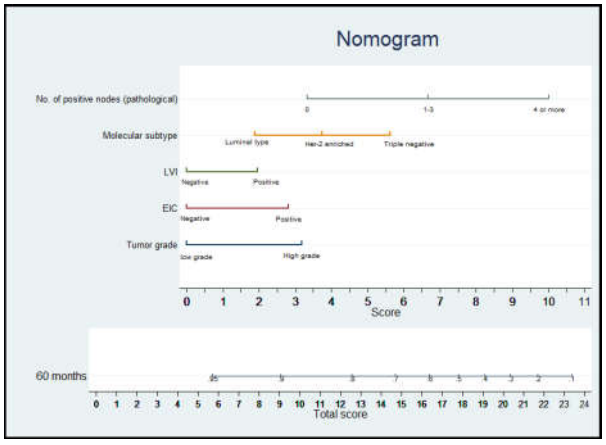

Figure 1 Overall 5-year survival nomogram.

Validation of the nomogram

The data from the internal validation set were used to validate the model. The calibration plot based on the data from the internal validation set for the probability of OS five years demonstrated excellent agreement between the prediction according to the nomogram and actual observation (Fig.2). The nomogram was found to have a c-index of 0.7196 for predicting the five year OS.

Next, the ROC was performed to validate the nomogram internally in the training set (Fig. 3A) and externally in the validation set (Fig.3B). In the training set, the AUC was 0.743 (95% CI: 0.690–0.796). In the validation set, the AUC was 0.753 (95% CI: 0.655–0.851). These results illustrated that the predicted and observed survival probabilities were in good concordance, and the goodness of fit of the nomogram was favourable.

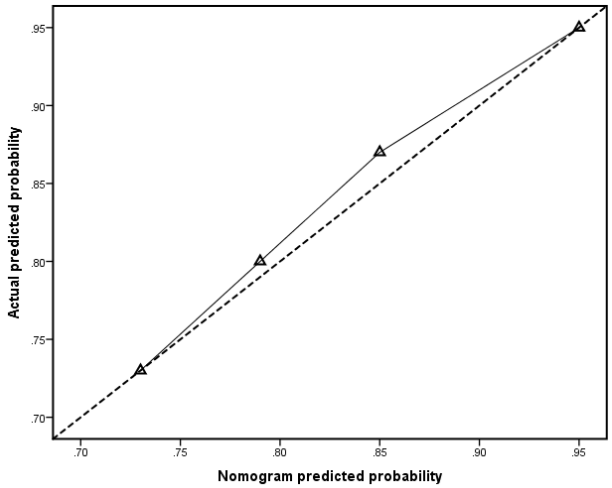

Figure 2 Calibration curves for 5-year overall survival. The dashed line indicates the ideal reference line where predicted probabilities would match the observed outcome. The solid line represents the performance of our current model (based on developed nomogram)

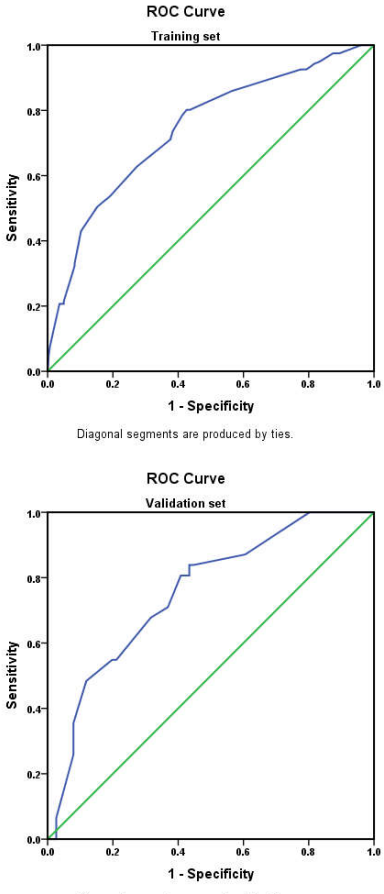

Figure 3 Predictive accuracy of the nomogram to predict OS in LABC by AUC in the training (A) and the validation set (B)

DISCUSSION

The need to devise a prognostic model able to help predict the prognosis of patients with breast cancer has recently become the focus of many studies. Accurate prediction of cancer control after definitive treatment for breast cancer is important for patient counseling, follow-up, and treatment planning.

Therefore, we constructed a nomogram based on a model to predict 5-year OS for patients with LABC who had undergone primary surgical treatment. The developed nomogram can be used to predict patients' prognosis individually and is based on the following 5 easily available parameters: tumor grade; molecular subtype; LVI; EIC and Number of positive nodes.

The prognostic factors for locally advanced tumors are similar to the prognostic factors for earlier breast cancer, with lymph node status and tumor size having the strongest effects on survival.[14] In the present study, we evaluated the prognostic values of several known predictors for survival of LABC patients. The association between the clinicopathologic factors and prognosis of LABC patients has been well established in previous studies[14-27] and was then confirmed in the present study. The effect of lymph node involvement was predominate in the nomogram. The total number of involved nodes is important prognostic information, as an increasing number of positive nodes portend worse survival. [14-19]

The role of hormone receptor status as a prognostic factor is less clear, but most of the studies have found that hormone receptor positivity is associated with a longer survival time. One study found that estrogen receptor positivity predicted a significantly longer disease-free interval and overall survival, but only in the subset of patients with operable breast cancer.[20] Another study of 187 patients with locally advanced tumors found that ER and PR negativity was associated with shorter overall survival times in univariate analysis.[21] In multivariate analysis also, PR status was still significantly associated with survival (hazard ratio = 0.54, 95 % confidence interval=0.35-0.83).[21] Recent attention has been directed singularly at molecular classifications of breast cancer.[22] The choice of Molecular classification factors introduced into this model was made based on their role in prognosis. Our study showed the triple negative subtype (ER/PR-, Her2-) has the worst OS compared to the other subtypes.[23] Similarly, histological factors, such as tumor grade, EIC and LVI have been found to influence survival in patients with breast cancer.[24-27]

In the present study, we confirmed the independent value of each of these factors as important parameters for prognosis thus strengthening the value of our nomogram as confirmed by a good C-index. The prediction model was internally validated using bootstrap resampling, assessing its optimism-corrected discrimination ability. The nomogram developed showed good discrimination ability with c-index of 0.7196. This c-index of our nomogram indicates its high predictive accuracy and is comparable with other published predictive nomograms of oral cancer, [28] and also with nomograms for other sites, such as the cervix and breast.[29-30]

Recently, a series of nomograms were published to improve the management of patients with LABC. Initially in a neoadjuvant setting, Rouzier *et al*. validated a nomogram able to predict the response to chemotherapy and survival in BC.[31] This nomogram included clinical and pathological factors such as ER and tumor grade and the prediction of prognosis was based on the interaction between four factors. Similarly, Keam *et al*. developed a nomogram to predict clinical outcomes in breast cancer patients treated with neoadjuvant chemotherapy.[32] Colleoni *et al*. proposed an approach to predict disease free survival with pathological factors but included biological parameters such as Ki-67 or HER2.[33] In an adjuvant setting, Mazouni *et al*. developed a nomogram to predict outcome after hormonal therapy but only incorporated classical prognostic factors.[34] Similarly Sun, Wei *et al*. proposed a model to predict OS and breast cancer-specific survival (BCSS) for patients with luminal breast cancer based on a SEER database.[35]

The nomograms provide probability estimates that might be useful at an individual level. For example, a locally advanced breast cancer female patient who has high tumor grade (Grade III) (3.5 points), triple negative molecular subtype (5.5 points) , with lymphovascular invasion involvement (2 points) , no extensive intraductal component (0 point) and more than four number of nodes positive (10.5 points) would have (21.5 total points) i.e. 30% probability of five year survival. Our nomogram includes more clinical and pathologic factors than TNM staging by adding predictive variables, such as Molecular subtypes, LVI and EIC. This allows the clinician to achieve a better estimation of the survival probability of an individual patient.

The nomogram we developed in this study could serve as both a scoring system and a visualized predicting tool, which could help physicians rapidly match a patient with her expected OS through a simple calculation in clinical practice.[9] In addition, this nomogram could assist in the clinical study design, balancing the prognostic background between different arms, especially for non-randomized data.[9]

Despite our nomogram having achieved prognostic accuracy, our study is not devoid of limitations. First, the retrospective nature of the database might result in bias and calls for prospective validation of the model. Second, the single-institutional nature of our dataset may be interpreted as a limitation, as demographic characteristics of the study cohort may be unique and may not be relevant in risk prediction of other patient populations. However, the study cohort being from a single institution had the advantage of having a uniform treatment policy, including postsurgical adjuvant therapy. Nevertheless, external validity of our model is a crucial prerequisite to clinical applicability, and can only be assessed by confirming results in a reasonably large independent validation cohort with an adequate follow-up period.

CONCLUSION

In conclusion, we developed and validated a novel nomogram for LABC patients. This nomogram provides a more accurate and precise prediction for 5-year OS in surgically treated This information will be useful for estimating prognosis and in guiding treatment selection.

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