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ARTICLE

# Development and Validation of a Nomogram Prediction Model for Moderate-to-Severe Acute Radiation Dermatitis in Patients with Breast Cancer: A Retrospective Study

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## Abstract

**Aims/Background** Acute radiation dermatitis is the most common complication of radiotherapy in patients with breast cancer, with mild severity relieved by symptomatic treatment and moderate-to-severe severity leading to compromised skin integrity and affecting the patient's quality of life. Therefore, this study aims to develop a prediction model for moderate-to-severe acute radiation dermatitis in patients with breast cancer to reduce its severity.

**Methods** A retrospective analysis of 713 patients receiving radiotherapy for breast cancer at the Affiliated Cancer Hospital of Xinjiang Medical University from January 2019 to December 2023 was conducted, with January 2019 to December 2021 serving as the training group (497 patients) and January 2022 to December 2023 serving as the validation group (216 patients). Patients in the training group were classified as having mild (383 patients) or moderately severe (114 patients) acute radiation dermatitis. Binary logistic regression was used to analyze the independent effects on moderately severe acute radiation dermatitis in patients with breast cancer, and a predictive model of the bar-folding plot was constructed and validated.

**Results** Univariable analysis revealed that age, body mass index, targeted therapy, oral tamoxifen use, hyperlipidemia, diabetes, positive regional lymph node metastasis, value-added index, and triple-negative breast cancer were factors influencing moderate-to-severe acute radiation dermatitis in patients with breast cancer. Multivariate analysis showed that body mass index, hyperlipidemia, diabetes, positive regional lymph node metastasis, and value-added index were independent influencing factors for moderate-to-severe acute radiation dermatitis in patients with breast cancer. A nomogram prediction model was constructed, and the area under the receiver operating characteristic curve of the model was 0.814 and 0.743 for internal and external validation, respectively. The calibration curve showed that the model predicted moderate-to-severe acute radiation dermatitis better, and the decision curve analysis curve showed that the model had a high clinical benefit.

**Conclusion** This risk prediction model can predict moderate-to-severe acute radiation dermatitis in patients with breast cancer, and help clinical providers screen high-risk patients and reduce acute radiation dermatitis severity.

**Key words: breast cancer; moderate-to-severe; acute radiation dermatitis; nomogram; predictive modelling**

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## Introduction

Breast cancer is one of the most common malignancies (Giaquinto et al, 2022). By 2022, there will be 20 million new cancers, including 2.3 million new cases of breast cancer, accounting for 11.6% of all cancer cases (Sung et al, 2021). Studies have shown that age, sex, family history, genetic mutations, estrogen, and an unhealthy lifestyle increase the risk of breast cancer (Majeed et al, 2014; Sun et al, 2017). Early screening and advances in medical technology have led to a 43% reduction in breast cancer mortality between 1989 and 2020 (Giaquinto et al, 2022). Breast cancer treatment is multidisciplinary in nature often requiring surgery, chemotherapy, and radiation therapy (Cardoso et al, 2019). Radical and total mastectomies for breast cancer result in breast removal, causing patients physical and psychological trauma. With technological advances and new radiotherapy techniques, breast-conserving surgery has become the treatment of choice for early-stage breast cancer, with 63% of patients undergoing this type of procedure (Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al, 2011). Breast-conserving surgery not only preserves the appearance of an intact breast but also has a positive psychological impact on the treatment of breast cancer patients. The survival rate of patients with breast cancer after breast-conserving surgery is the same as that after radical mastectomy (Veronesi et al, 2002). Postoperative radiotherapy can reduce local tumour recurrence and mortality rates, and breast-conserving postoperative radiotherapy has become one of the treatments for breast cancer (Speers and Pierce, 2016; Valente and Shah, 2020).

Radiotherapy can lead to several common complications, such as acute or chronic skin, heart, and lung damage. Acute radiation dermatitis (ARD) occurs within 90 days after the first radiotherapy session, with an incidence of 90–95%, of which 25–30% progress to moderate-to-severe radiation dermatitis (Ben Amor et al, 2023). ARD not only causes sleep and anxiety disorders in patients, affecting their quality of life, but also leads to delayed or early termination of the radiotherapy regimen, thereby reducing the effectiveness of treatment. Although mild ARD can be relieved with symptomatic treatment, severe cases can impair skin integrity and increase infection risk (Ramadan et al, 2021). In previous studies analyzing the factors influencing radiation dermatitis, Qin et al (2023) found that a pre-radiotherapy Th/Ts ratio and a mid-radiotherapy serum albumin level $<35$ g/L impact radiodermatitis in nasopharyngeal carcinoma. Liu et al (2022) identified body mass index $>24$, lack of protective medication for localized skin issues during radiotherapy, and positive regional lymph node metastasis as factors influencing radiation dermatitis in patients with breast cancer. Chugh et al (2021) reported that higher age, higher tumour node metastasis stage, and concurrent chemotherapy influenced radiation dermatitis in patients with head and neck cancer. Ciammella et al (2014) indicated that both an additional dose of radiotherapy and the presence of diabetes were influencing factors in the development of radiation dermatitis in patients with breast cancer. Xie et al (2023) found that body mass index, diabetes, smoking, high ferritin levels, and high $CD3^+$ T lymphocyte levels were influencing factors

for grade 4 radiation dermatitis. This study aimed to identify the factors influencing moderate to severe ARD in breast cancer.

A nomogram is a straightforward tool for predicting clinical outcomes (Wu et al, 2020). Nomograms have a wide range of applications in various fields, such as disease prediction (Du et al, 2018), survival rate projection (Liang et al, 2015), disease recurrence prediction (Huang et al, 2021), and prognosis (Ren et al, 2023). Previous studies have analyzed the factors influencing radiodermatitis, but there are fewer predictors of acute radiation dermatitis for each grade and relatively few predictive models for the breast cancer radiodermatitis nomogram. Therefore, in this study, we precisely stratified breast cancer ARD to reduce the severity of second- and third-degree ARD. Logically, the higher the radiotherapy dose, the higher the skin and mucosal toxicities. In this study, patients with breast cancer receiving the same radiotherapy dose and modality were analyzed to identify other influencing factors of moderate-to-severe ARD in patients with breast cancer and to construct a nomogram prediction model with the aim of providing a reference for the prevention, assessment, and care of moderate-to-severe ARD in patients with breast cancer.

# Methods

## Study Design and Population

A retrospective analysis of 713 patients undergoing radiotherapy for breast cancer in a tertiary-level hospital in Xinjiang was conducted from the beginning of January 2019 to the end of December 2023, and this study was approved by the ethics committee of the Affiliated Cancer Hospital of Xinjiang Medical University (K-2022035).

The inclusion criteria were as follows: (i) age $\geq$18 years; (ii) having undergone breast-conserving surgery, followed by large division intensity-modulated radiotherapy, and (iii) having undergone a total of 45.56 Gy+10 Gy/16+5 times of radiotherapy.

The exclusion criteria were as follows: (i) history of previous radiotherapy; or (ii) incomplete clinical data. After meeting the inclusion criteria, 713 patients were included in the study (Fig. 1). According to the requirements of epidemiological studies, each included factor required 5–10 samples for validation (Shipe et al, 2019). In this study, 22 influencing factors were initially formulated. The patients were randomly divided into a modelling group (497 patients) and a validation group (216 patients) in a 7:3 ratio. The modelling group was used to construct a predictive model for the nomogram of moderate-to-severe ARD in patients with breast cancer, and the validation group was used for external validation of the model.

## Research Tools

The literature research method, group discussion method (there were five members in the group, including one postgraduate supervisor in breast cancer, one nursing administrator in the radiotherapy department, one nurse practitioner, one physician who had been engaged in the first-line clinical work of the breast radiother-

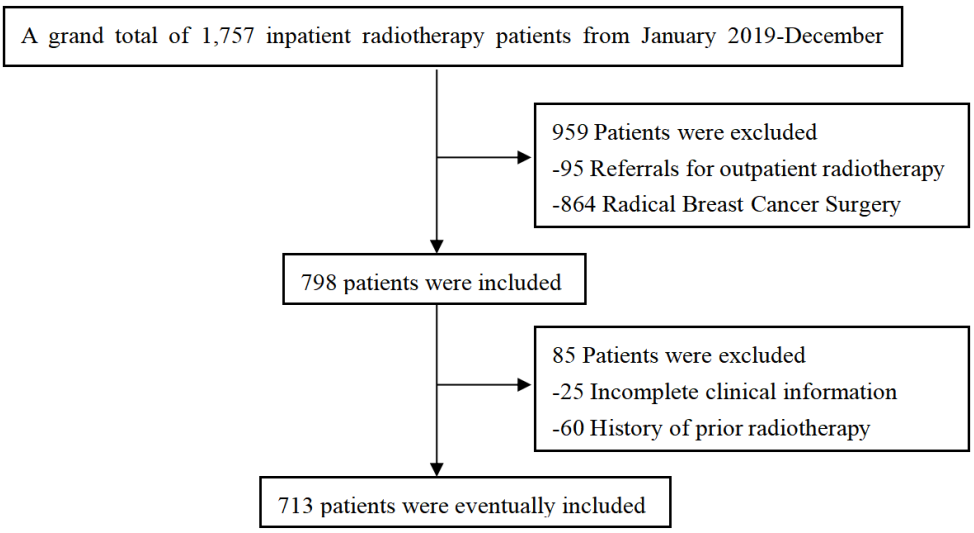


**Fig. 1. Flow diagram outlining the search progress.**

apy department for more than 15 years, and one postgraduate student in nursing), and data collected by the clinic were used. Data collection included the following three aspects: (i) general basic information, such as age, body mass index (BMI), which was classified into four categories as defined by the World Health Organization (WHO) (<18.5 as wasting; 18.5 to 23.9 as normal; 24 to 27.9 as overweight; and >28 as obese), occupation, and education level; general clinical information, such as tumour location, chemotherapy, endocrine therapy, targeted therapy, oral tamoxifen use, hyperlipidemia, anemia, fatty liver, diabetes, tumour diameter, regional lymph node metastasis (LNM) positive status, and triple negative breast cancer; and laboratory test results, including value-added index, Ki67, red blood cell (RBC) count, white blood cell (WBC) count, platelet (PLT) count, and levels of serum albumin (ALB) and hemoglobin (HB).

## Data Collection Methods

The data were collected using the hospital medical record system, verified, and entered by three individuals. Additionally, 10% of the data were selected for review by a fourth researcher to ensure that they had been entered correctly. The severity of ARD and objective indices were observed at the end of the last radiotherapy session.

## Evaluation Indicators

The Radiation Therapy Oncology Group Grading Criteria (Cox et al, 1995), issued by the American Collaborative Group for Radiation Therapy of Oncology in 1995, classifies ADR into five grades: grade 0, essentially unchanged; grade I, mild follicular erythema, dry desquamation, and decreased sweating; grade II, bright red erythema, pain, mottled wet desquamation, and moderate edema; grade III, fused wet desquamation and depressed edema; and grade IV, which includes

ulceration, hemorrhage, and necrosis. In this study, breast cancer ARD grade I and grades II and III were mild and moderately severe, respectively.

### Statistical Methods

SPSS 25.0 (IBM Corp, Armonk, NY, USA), R 4.3.1 (University of Auckland, Auckland, New Zealand), and R-shiny (https://www.shinyapps.io/) were used for the data analysis, model construction, and model validation. Measurement data conforming to a normal distribution were statistically described by mean ± standard deviation ($\bar{x} \pm s$), and a *t*-test was used for comparison between groups. Non-normally distributed measurements were statistically described by median and quartile [M (P25, P75)], and the Mann-Whitney rank sum test was used for comparisons between groups. Count data were statistically described by frequency and percentage (%), and comparisons between groups were made using the $\chi^2$ test or Fisher's exact probability test. The modelling group performed model construction using moderate-to-severe ARD of patients with breast cancer as the dependent variable and the general information questionnaire as the independent variable in the one-way analysis of variance, and variables with $p < 0.05$ in the one-way analysis were included in the binary logistic regression model. The nomogram prediction model was constructed using R 4.3.1 (University of Auckland, Auckland, New Zealand). R-shiny were used to visualize the nomogram. The validation group underwent external validation. The data of both the modelling and validation groups were analyzed using the area under the receiver operating characteristic (ROC) curve to assess the discrimination ability of the prediction model. The Hosmer-Lemeshow test was used to assess the goodness-of-fit of the response model, sensitivity and specificity to validate the predictive efficacy of the model, the calibration curve to assess the calibration of the model, and the decision curve analysis (DCA) curve was used to assess its clinical usefulness.

## Results

### Patient Characteristics

A total of 713 patients with breast cancer were included in the study, with a mean age of 51.20 ± 9.90 years. The modelling group included 497 patients with breast cancer experiencing ARD, of which 383 (77.1%) cases were mild and 114 (22.9%) were moderately severe; the patients' ages ranged from 21 to 84 (51.20 ± 9.90) years. In the validation group, 216 patients with breast cancer experiencing ARD were included, of which 181 (83.8%) cases were mild and 35 (16.2%) were moderately severe; the patients' ages ranged from 28 to 85 (51.04 ± 9.02) years, as shown in Table 1.

### Construction of a Prediction Model for Moderate-to-Severe ARD in Patients with Breast Cancer

The single-factor analysis is shown in Table 2, and the assignment method is shown in Table 3. Age was carried forward to its original value. The BMI was divided into four categories as defined by the WHO, and the remaining seven variables were assigned values of yes or no. The multifactor analysis is shown

**Table 1. General information on acute radiation dermatitis (ARD) in patients with breast cancer (n = 713).**

| Variable | Total (n = 713) | Modelling group (n = 497) | Validation group (n = 216) | Statistical value | *p*-value |
|---|---|---|---|---|---|
| Age ($\bar{x} \pm s$, year) | 51.20 ± 9.90 | 51.20 ± 9.90 | 51.04 ± 9.02 | $t = 0.203$ | 0.839 |
| BMI [n (%)] | | | | $\chi^2 = 6.396$ | 0.094 |
| <18.5 | 36 (5.0) | 23 (4.6) | 13 (6.0) | | |
| 18.5–23.9 | 287 (40.3) | 188 (37.8) | 99 (45.8) | | |
| 24–27.9 | 348 (48.8) | 258 (51.9) | 90 (41.7) | | |
| ≥28 | 42 (5.9) | 28 (5.7) | 14 (6.5) | | |
| Occupation [n (%)] | | | | $\chi^2 = 5.802$ | 0.122 |
| Peasant | 65 (9.1) | 51 (10.3) | 14 (6.5) | | |
| Professional | 79 (11.1) | 48 (9.7) | 31 (14.4) | | |
| Retired | 172 (24.1) | 117 (23.5) | 55 (25.5) | | |
| Other | 397 (55.7) | 281 (56.5) | 116 (53.6) | | |
| Educational attainment [n (%)] | | | | $\chi^2 = 6.353$ | 0.096 |
| Below junior high school | 364 (51.1) | 265 (53.3) | 99 (45.8) | | |
| High school or junior college | 75 (10.5) | 55 (11.1) | 20 (9.3) | | |
| Three-year college | 218 (30.6) | 138 (27.8) | 80 (37.0) | | |
| Undergraduate or higher | 56 (7.8) | 39 (7.8) | 17 (7.9) | | |
| Tumour location [n (%)] | | | | $\chi^2 = 3.122$ | 0.210 |
| Left breast | 373 (52.3) | 264 (53.1) | 109 (50.5) | | |
| Right breast | 329 (46.1) | 223 (44.9) | 106 (49.1) | | |
| Both breasts | 11 (1.6) | 10 (2.0) | 1 (0.4) | | |
| Chemotherapy [n (%)] | | | | $\chi^2 = 1.146$ | 0.284 |
| Yes | 411 (57.6) | 280 (56.3) | 131 (60.6) | | |
| No | 302 (42.4) | 217 (43.7) | 85 (39.4) | | |
| Endocrine therapy [n (%)] | | | | $\chi^2 = 0.992$ | 0.319 |
| Yes | 544 (76.3) | 374 (75.3) | 170 (78.7) | | |
| No | 169 (23.7) | 123 (24.7) | 46 (21.3) | | |
| Targeted therapies [n (%)] | | | | $\chi^2 = 0.698$ | 0.403 |
| Yes | 80 (11.2) | 59 (11.9) | 21 (9.7) | | |
| No | 633 (88.8) | 438 (88.1) | 195 (90.3) | | |
| Oral tamoxifen [n (%)] | | | | $\chi^2 = 2.920$ | 0.088 |
| Yes | 309 (43.3) | 205 (41.2) | 104 (48.1) | | |
| No | 404 (56.7) | 292 (58.8) | 112 (51.9) | | |
| Hyperlipidemia [n (%)] | | | | $\chi^2 = 2.967$ | 0.085 |
| Yes | 56 (7.9) | 33 (6.6) | 23 (10.6) | | |
| No | 657 (92.1) | 464 (93.4) | 193 (89.4) | | |
| Anemia [n (%)] | | | | $\chi^2 = 2.758$ | 0.097 |
| Yes | 58 (8.1) | 46 (9.3) | 12 (5.6) | | |
| No | 655 (91.9) | 451 (90.7) | 204 (94.4) | | |
| Fatty liver [n (%)] | | | | $\chi^2 = 2.999$ | 0.083 |
| Yes | 244 (34.2) | 160 (32.2) | 84 (38.9) | | |
| No | 469 (65.8) | 337 (67.8) | 132 (61.1) | | |

**Table 1. Continued.**

| Variable | Total (n = 713) | Modelling group (n = 497) | Validation group (n = 216) | Statistical value | *p*-value |
|---|---|---|---|---|---|
| Diabetes [n (%)] | | | | $\chi^2 = 0.638$ | 0.424 |
| Yes | 83 (11.6) | 61 (12.3) | 22 (10.2) | | |
| No | 630 (88.4) | 436 (87.7) | 194 (89.8) | | |
| Tumour diameter [n (%)] | | | | $\chi^2 = 4.261$ | 0.119 |
| <1 cm | 126 (17.7) | 94 (18.9) | 32 (14.8) | | |
| 1–5 cm | 525 (73.6) | 355 (71.4) | 170 (78.7) | | |
| >5 cm | 62 (8.7) | 48 (9.7) | 14 (6.5) | | |
| LNM [n (%)] | | | | $\chi^2 = 0.819$ | 0.365 |
| Yes | 140 (19.6) | 102 (20.5) | 38 (17.6) | | |
| No | 573 (80.4) | 395 (79.5) | 178 (82.4) | | |
| Ki67 [n (%)] | | | | $\chi^2 = 0.101$ | 0.751 |
| Low expression | 267 (37.4) | 188 (37.8) | 79 (36.6) | | |
| High expression | 446 (62.6) | 309 (62.2) | 137 (63.4) | | |
| Triple-negative breast cancer [n (%)] | | | | $\chi^2 = 0.957$ | 0.328 |
| Yes | 117 (16.4) | 86 (17.3) | 31 (14.4) | | |
| No | 596 (83.6) | 411 (82.7) | 185 (85.6) | | |
| Severity [n (%)] | | | | $\chi^2 = 3.733$ | 0.053 |
| Mild | 564 (79.1) | 383 (77.1) | 181 (83.8) | | |
| Moderately severe | 149 (20.9) | 114 (22.9) | 35 (16.2) | | |
| RBC ([M (P25, P75)], g/L) | 4.30 (4.08, 4.55) | 4.30 (4.08, 4.54) | 4.31 (4.05, 4.56) | Z = –0.352 | 0.725 |
| WBC ([M (P25, P75)], g/L) | 4.16 (3.52, 5.06) | 4.15 (3.47, 5.06) | 4.13 (3.55, 4.86) | Z = –0.378 | 0.706 |
| PLT ([M (P25, P75)], g/L) | 203.00 (168.00, 240.00) | 204.00 (170.00, 241.00) | 200.00 (161.25, 236.00) | Z = –1.249 | 0.212 |
| ALB ([M (P25, P75)], g/L) | 41.50 (39.40, 43.70) | 41.60 (39.50, 44.00) | 41.25 (39.12, 43.17) | Z = –1.812 | 0.070 |
| HB ([M (P25, P75)], g/L) | 130.00 (122.00, 138.00) | 130.00 (121.00, 137.00) | 131.00 (125.00, 138.75) | Z = –2.349 | 0.059 |

BMI, body mass index; LNM, lymph node metastasis positive; Ki67, value-added index; RBC, red blood cell count; WBC, white blood cell count; PLT, platelet count; ALB, albumin; HB, hemoglobin.

in Table 4. Logistic regression equations were constructed based on the above-influencing factors: logit $p = 0.407 \times$ BMI + 1.109 × hyperlipidemia + 3.148 × diabetes + 0.947 × LNM + 0.650 × Ki67 – 2.810 and plotted in R 4.3.1 (University of Auckland, Auckland, New Zealand) using the breast cancer moderate-severe ARD nomogram prediction model (Fig. 2). The nomogram was used to determine scores corresponding to each factor in the graph. Based on the scale above the corresponding nomogram of the variables, we obtained an individual score for each one. All variable scores were summed to obtain a total score. The higher the total score, the higher the risk of moderate-to-severe ARD. Ultimately, the incidence of breast cancer with moderate-to-severe ARD could be determined.

**Table 2. One-way analysis of severe ARD in patients with breast cancer (n = 497).**

| Variable | Mildly severe (n = 383) | Moderately severe (n = 114) | Statistical value | *p*-value |
|---|---|---|---|---|
| Age ($\bar{x} \pm s$, year) | 50.64 ± 9.91 | 53.10 ± 9.66 | $t = -2.339$ | 0.020 |
| BMI [n (%)] | | | $\chi^2 = 16.069$ | 0.001 |
| <18.5 | 15 (3.9) | 8 (7.0) | | |
| 18.5–23.9 | 158 (41.3) | 30 (26.3) | | |
| 24–27.9 | 195 (50.9) | 63 (55.3) | | |
| ≥28 | 15 (3.9) | 13 (11.4) | | |
| Occupation [n (%)] | | | $\chi^2 = 3.749$ | 0.290 |
| Peasant | 42 (11.2) | 9 (7.8) | | |
| Professional | 34 (8.8) | 14 (12.3) | | |
| Retired | 85 (22.1) | 32 (28.1) | | |
| Other | 222 (57.9) | 59 (51.8) | | |
| Educational attainment [n (%)] | | | $\chi^2 = 5.631$ | 0.131 |
| Below junior high school | 206 (53.8) | 59 (51.8) | | |
| High school or junior college | 36 (9.4) | 19 (16.7) | | |
| Three-year college | 108 (28.2) | 30 (26.3) | | |
| Undergraduate or higher | 33 (8.6) | 6 (5.2) | | |
| Tumour location [n (%)] | | | $\chi^2 = 1.103$ | 0.576 |
| Left breast | 208 (54.3) | 56 (49.1) | | |
| Right breast | 168 (43.9) | 55 (48.2) | | |
| Both breasts | 7 (1.8) | 3 (2.7) | | |
| Chemotherapy [n (%)] | | | $\chi^2 = 1.055$ | 0.304 |
| Yes | 211 (55.1) | 69 (60.5) | | |
| No | 172 (44.9) | 45 (39.5) | | |
| Endocrine therapy [n (%)] | | | $\chi^2 = 0.299$ | 0.584 |
| Yes | 286 (74.7) | 88 (77.2) | | |
| No | 97 (25.3) | 26 (22.8) | | |
| Targeted therapies [n (%)] | | | $\chi^2 = 4.550$ | 0.033 |
| Yes | 39 (10.2) | 20 (17.5) | | |
| No | 344 (89.8) | 94 (82.5) | | |
| Oral tamoxifen [n (%)] | | | $\chi^2 = 5.706$ | 0.017 |
| Yes | 169 (44.1) | 36 (31.6) | | |
| No | 214 (55.9) | 78 (68.4) | | |
| Hyperlipidemia [n (%)] | | | $\chi^2 = 7.593$ | 0.006 |
| Yes | 19 (5.0) | 14 (12.3) | | |
| No | 364 (95.0) | 100 (87.7) | | |
| Anemia [n (%)] | | | $\chi^2 = 2.682$ | 0.101 |
| Yes | 31 (8.1) | 15 (13.2) | | |
| No | 352 (91.9) | 99 (86.8) | | |
| Fatty liver [n (%)] | | | $\chi^2 = 2.070$ | 0.150 |
| Yes | 117 (30.5) | 43 (37.7) | | |
| No | 266 (69.5) | 71 (62.3) | | |

**Table 2. Continued.**

| Variable | Mildly severe (n = 383) | Moderately severe (n = 114) | Statistical value | *p*-value |
|---|---|---|---|---|
| Diabetes [n (%)] | | | $\chi^2 = 129.564$ | <0.001 |
| Yes | 12 (3.1) | 49 (43.0) | | |
| No | 371 (96.9) | 65 (57.0) | | |
| Tumour diameter [n (%)] | | | $\chi^2 = 3.731$ | 0.155 |
| <1 cm | 76 (19.8) | 18 (15.8) | | |
| 1–5 cm | 275 (71.8) | 80 (70.2) | | |
| >5 cm | 32 (8.4) | 16 (14.0) | | |
| LNM [n (%)] | | | $\chi^2 = 16.991$ | <0.001 |
| Yes | 63 (16.4) | 39 (34.2) | | |
| No | 320 (83.6) | 75 (65.8) | | |
| Ki67 [n (%)] | | | $\chi^2 = 8.335$ | 0.004 |
| Low expression | 158 (41.3) | 30 (26.3) | | |
| High expression | 225 (58.7) | 84 (73.7) | | |
| Triple-negative breast cancer [n (%)] | | | $\chi^2 = 14.015$ | <0.001 |
| Yes | 53 (13.8) | 33 (28.9) | | |
| No | 330 (86.2) | 81 (71.1) | | |
| RBC ([M (P25, P75)], g/L) | 4.29 (4.08, 4.54) | 4.30 (4.08, 4.53) | Z = –0.007 | 0.994 |
| WBC ([M (P25, P75)], g/L) | 4.16 (3.46, 5.10) | 4.12 (3.56, 4.81) | Z = –0.284 | 0.776 |
| PLT ([M (P25, P75)], g/L) | 206.00 (173.00, 241.00) | 197.50 (163.25, 242.00) | Z = –1.334 | 0.182 |
| ALB ([M (P25, P75)], g/L) | 41.80 (39.50, 44.00) | 41.35 (39.67, 43.90) | Z = –0.348 | 0.728 |
| HB ([M (P25, P75)], g/L) | 130.00 (121.00, 138.00) | 129.00 (120.00, 135.25) | Z = –1.202 | 0.229 |

## Validation of a Predictive Model for Moderate-to-Severe ARD in Patients with Breast Cancer

### *Differentiation Ability of the Model*

The ROC curves corresponding to the subjects in the modelling and validation groups were plotted (Fig. 3A,B). The area under the curve (AUC) of the modelling group was 0.814 (95% confidence interval (CI): 0.766–0.862), C-index = 0.803, sensitivity: 0.867, specificity: 0.614. The AUC of the validation group was 0.743 (95% CI: 0.629–0.857), C-index = 0.877, sensitivity: 0.956, specificity: 0.543. An AUC of 0.5–0.7 indicated a low predictive value; an AUC of 0.7–0.9 indicated a good predictive effect; and an AUC >0.9 indicated an excellent predictive effect.

### *Calibration Ability of the Models*

The calibration curve was used to visualize the relationship between the predicted probability values and the actual probability values of the nomogram (Fig. 4A,B). The x-axis represents the predicted probability of severe acute radiation dermatitis in patients with breast cancer, whereas the y-axis represents the actual probability of them developing severe acute radiation dermatitis. If the solid line coincides ex-

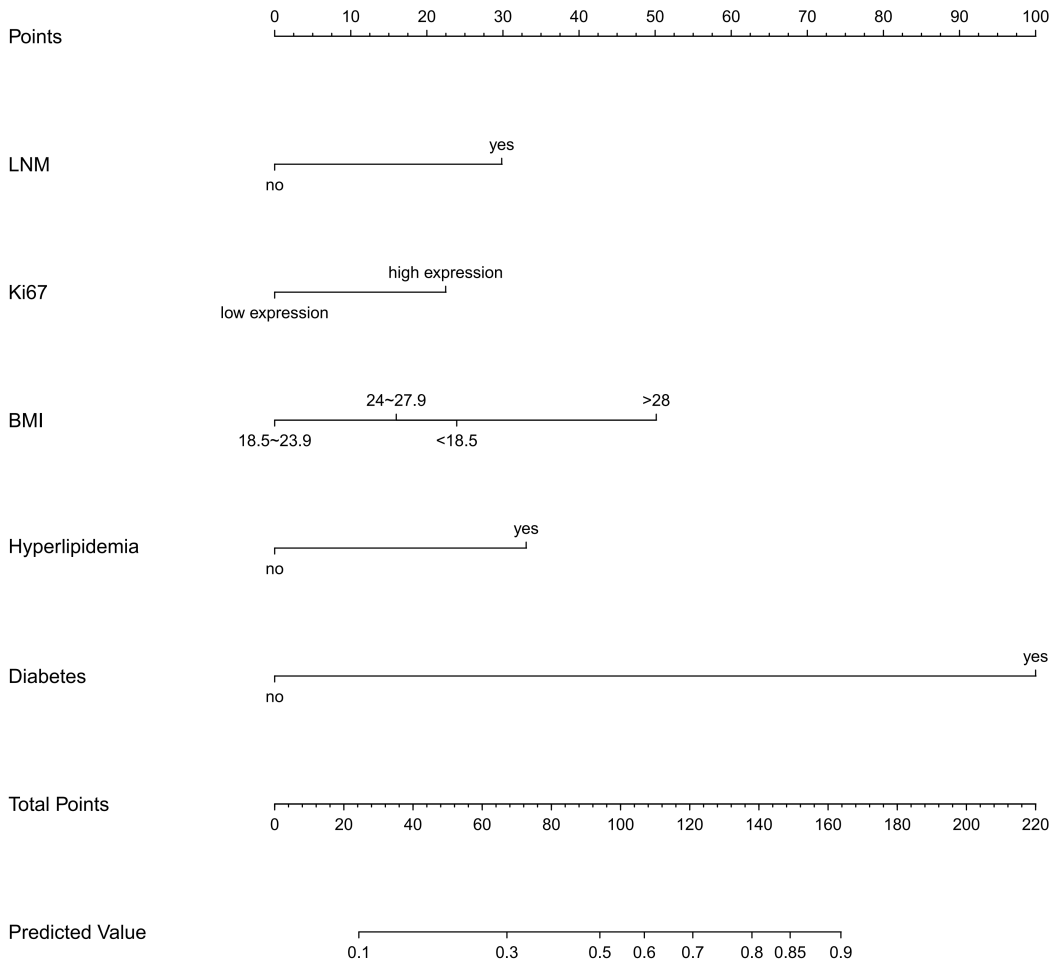


**Fig. 2. Nomogram prediction model for moderate-to-severe ARD in patients with breast cancer.**

**Table 3. Assignment methods of severe ARD in patients with breast cancer.**

| Variable | Assignment method |
|---|---|
| Age | Original value |
| BMI | 0: <18.5, 1: 18.5–23.9, 2: 24–27.9, 3: ≥28 |
| Targeted therapies | 0 = No, 1 = Yes |
| Oral tamoxifen | 0 = No, 1 = Yes |
| Hyperlipidemia | 0 = No, 1 = Yes |
| Diabetes | 0 = No, 1 = Yes |
| LNM | 0 = No, 1 = Yes |
| Ki67 | 0 = Low expression, 1 = High expression |
| Triple-negative breast cancer | 0 = No, 1 = Yes |

actly with the dashed line, the model is optimal. The calibration curves in this study showed good agreement between predictions of the occurrence of severe ARD in patients with breast cancer and the actual probability of occurrence in the nomogram. In addition, the nomogram prediction models were found to be in good agreement in the modelling and validation groups with the Hosmer-Lemeshow test of $\chi^2$ value

**Table 4. Multivariate analysis of severe ARD in patients with breast cancer.**

| Variable | Regression coefficient | Standard error | Wald $\chi^2$ | *p*-value | OR worth | 95% CI |
|---|---|---|---|---|---|---|
| BMI | 0.407 | 0.192 | 4.509 | 0.034 | 1.502 | 1.032–2.187 |
| Hyperlipidemia | 1.109 | 0.443 | 6.277 | 0.012 | 3.032 | 1.273–7.221 |
| Diabetes | 3.148 | 0.387 | 66.139 | <0.001 | 23.295 | 10.908–49.749 |
| LNM | 0.947 | 0.291 | 10.599 | 0.001 | 2.579 | 1.458–4.561 |
| Ki67 | 0.650 | 0.288 | 5.087 | 0.024 | 1.916 | 1.089–3.372 |
| Constant | –2.810 | 0.854 | 10.833 | 0.001 | 0.060 | |

Notes: Odds ratio (OR): Values are called specific potential ratios and reflect the strength of the association between the disease and exposure.
Confidence interval (CI): Range within which the overall parameter is estimated with a certain probability. The 95% confidence interval was within the 95% range.

= 5.053 ($p$ = 0.752) and $\chi^2$ value = 6.311 ($p$ = 0.612). The $p$-values for both the modelling and validation groups were >0.05, indicating that the model was well-calibrated.

### *Clinical Benefits of the Model*

The DCA curves of the modelling and validation groups were plotted (Fig. 5A,B), and the DCA results for the modelling group showed a positive net effect with a threshold probability of 0–0.86. The model exhibited a positive net effect, and in the validation group, when the threshold probability was 0–0.84, the model also exhibited a positive net effect, indicating that the nomogram prediction model had good clinical predictive ability.

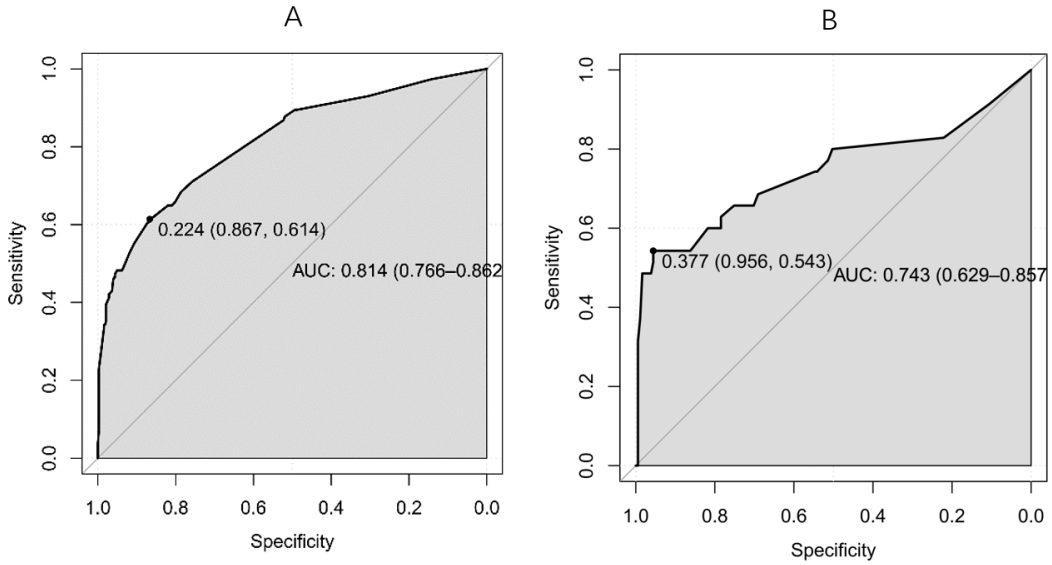


**Fig. 3. Receiver operating characteristic (ROC) curves of the nomogram prediction model for moderate-to-severe ARD in patients with breast cancer.** (A) Training set. (B) Test set. AUC, area under the curve.

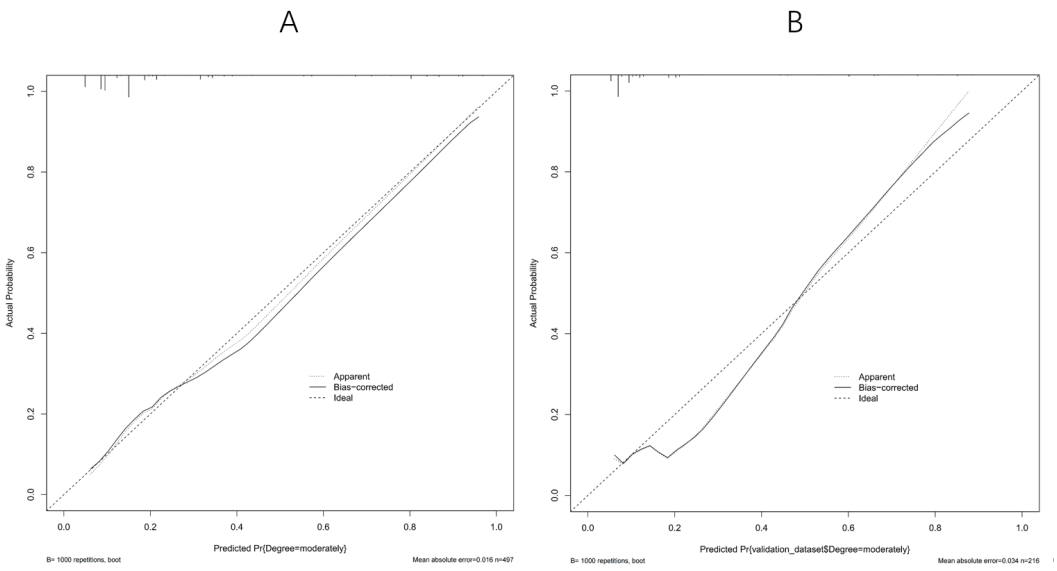


**Fig. 4. Calibration curves of the nomogram prediction model for moderate-to-severe ARD in patients with breast cancer.** (A) Training set. (B) Test set.

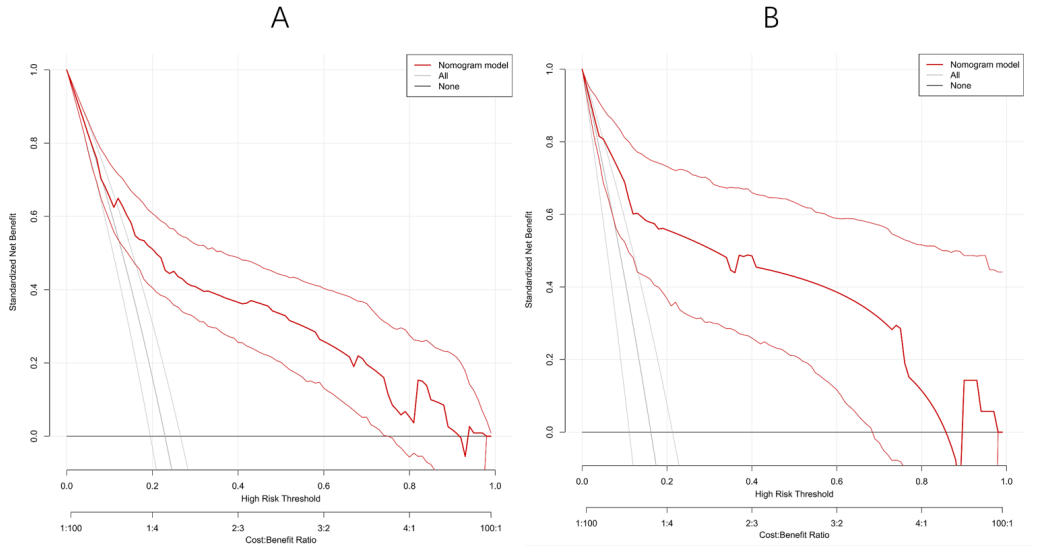


**Fig. 5. Decision curve analysis (DCA) curves of the nomogram prediction model for moderate-to-severe ARD in patients with breast cancers.** (A) Training set. (B) Test set.

# Discussion

## Individual Patient Factors

Obesity is defined as the accumulation of fat, which adversely affects health (van der Klaauw and Farooqi, 2015). Obesity is associated with increased cancer risk and mortality (Bhaskaran et al, 2014). The BMI, a method of defining obesity used by the WHO, was shown to be an influencing factor in moderate-to-severe ARD in patients with breast cancer in this study. This finding is consistent with those reported by Rattay et al (2020). The higher the BMI, the larger the breast size of the patient, resulting in a larger, more uneven irradiation dose and skinfold fric-

tion during radiotherapy, worsening the local skin reaction to radiotherapy. A BMI >24 is considered overweight or obese. Obesity leads to abnormal metabolism of adipose tissue, which affects the release of various hormones, enzymes, free fatty acids, adipokines, and inflammatory factors (Kahn et al, 2019), resulting in hyperlipidemia. Obese people are also likely to sweat profusely, which exposes the skin to moisture for a prolonged period, weakening skin integrity. Moreover, radiotherapy directly damages the treated skin, with a larger dose resulting in more severe radiation dermatitis (Dissemond et al, 2021).

### Disease and Treatment-Related Factors

The results of this study show that diabetes has an independent influence on the development of moderate-to-severe ARD in patients with breast cancer. This finding is consistent with those of Xie et al (2023). Their study showed that type 2 diabetes increases the risk of cancer, especially breast, endometrial, and colorectal cancers (Tsilidis et al, 2015). Hyperglycemia leads to systemic complications and a range of pathological changes in the wounded site, including dysregulated angiogenesis, chronic inflammation, and hypoxia-induced oxidative stress (Baltzis et al, 2014). All patients in this study had type 2 diabetes, which negatively affected wound healing (Ogurtsova et al, 2022). Diabetes allows acute injuries to progress to chronic ones, severely affecting patient prognosis and quality of life (Wolcott et al, 2016). Healthcare professionals should promptly assess the localized skin issues of patients with diabetes, record them, and strictly control blood glucose levels to avoid exacerbating skin problems. The results of this study also showed that positive LNM was an influencing factor in the development of moderate-to-severe ARD in patients with breast cancer, consistent with the findings of Liu et al (2022). Breast cancer mainly spreads and metastasizes through the axillary lymph nodes. Axillary lymph node metastasis is the main reference point for the surgical approach and development of the radiation field (Verma et al, 2023). In cases of axillary lymph node metastasis, axillary lymph node dissection is needed, which results in greater damage to the surrounding tissues and increases the scope of the radiation field, leading to changes in the local skin and soft tissues and aggravation of the skin's reaction to radiotherapy (De Langhe et al, 2014). In addition, a series of complications occur after axillary lymph node dissection, such as limited activity of the upper limb on the operated-on side and upper limb lymphedema, which affects patients' quality of life. In clinical practice, medical personnel should guide patients in performing exercises to promote the recovery of upper limb function and to facilitate the patients' return to normal activities. Research indicates that Ki67 is an independent predictor of breast cancer, with higher values suggesting that the tumour is more malignant, more actively proliferating, and more sensitive to radiotherapy (Pu et al, 2019). Simultaneously, Ki67 is of great significance for the selection of postoperative treatment programs for breast cancer, as it affects the prognosis of patients with breast cancer. Therefore, when healthcare professionals formulate nursing plans for patients with breast cancer, they should also consider the biochemical indices and strengthen skin management for patients with a high value-added index.

The prediction model constructed in this study has the following advantages. First, it can accurately predict the likelihood of moderate-to-severe ARD in patients with breast cancer, with an area under the ROC curve as high as 0.822. Second, the model helps radiotherapy patients actively implement self-management of skin conditions. Third, by predicting the incidence of moderate-to-severe ARD, the model can provide important information for healthcare professionals and help them make important clinical decisions early on. Finally, as a tool, the model is easier to use than previous ones and facilitates clinical decision-making.

Nonetheless, there is great potential for assessing the risk of moderate-to-severe ARD in patients with breast cancer early on using a nomogram prediction model that can be applied online, making it a low-cost and reliable method for the prediction of moderate-to-severe ARD. In the future, we hope that patients with breast cancer will be able to enter their symptoms and obtain prediction results via appropriate platforms, and healthcare professionals will be able to remotely view the patient's status and make timely decisions based on their expertise. The prediction model can not only guide the early detection and treatment of moderate-to-severe ARD in patients with breast cancer and reduce its severity but also encourage and help patients with breast cancer undergoing radiotherapy to participate in the management of their skin conditions, which could be useful for the prospective monitoring and management of ARD in both preclinical and clinical settings. It is recommended that the healthcare team educate patients undergoing radiotherapy for breast cancer to enhance trust, which will, in turn, improve the adherence of patients and the effect of radiotherapy. It is recommended that practitioners provide comprehensive care for patients with breast cancer receiving radiotherapy through pre-hospital-in-hospital-post-hospital phased management, which would resolve each patient's doubts, address each patient's needs during hospitalization, and offer individualized guidance to strengthen each patient's confidence in the self-management of skin issues. The follow-up method involved establishing a WeChat group for regular follow-ups with breast cancer radiotherapy patients at 1, 3, and 6 months and at 1 and 3 years after discharge and enabling medical personnel to answer patients' questions daily and to resolve their skin problems after discharge.

### Limitations

There were some limitations in this study. First, all cases included in this study were from a single center, which inevitably produced bias. Second, this study used a retrospective design. Therefore, it requires a prospective study at a later stage, and the model constructed in this study would require a multicenter and large-sample study. Finally, the population included in this study was limited to patients with breast cancer experiencing ARD treated with in-hospital radiotherapy, and a standardized process must be established for ensuring the continuity of skin care after patients are discharged from the hospital.

## Conclusion

In this study, a prediction model containing five variables was constructed to screen out patients with a higher risk of moderate-to-severe ARD, and the estab-

lishment of a risk prediction model enabled healthcare professionals to utilize the relevant resources more rationally, grasp changes in the skin of the patients in a timely and accurate manner, and implement targeted preventive measures for high-risk patients to ultimately reduce the extent of ARD.

### Practical Implications

Clinicians can use the risk factors identified in this study to develop targeted assessment and intervention plans, particularly for patients at a higher risk of moderate-to-severe radiodermatitis. For example, incorporating routine screening for risk factors for moderate-to-severe ARD in patients with breast cancer into the radiotherapy planning phase would not only improve the overall quality of life of patients undergoing radiotherapy for breast cancer but also enhance the effectiveness of their radiotherapy treatment.

### Nursing Practice Implications

Skin protection is crucial in breast cancer radiotherapy. Nurses play an integral role in assessing and caring for patients undergoing radiotherapy. The aim of this study is to develop a nomogram prediction model for moderate-to-severe radiation dermatitis in patients undergoing radiotherapy for breast cancer to provide a specific assessment tool for nurses. The nomogram helps practitioners accurately and effectively implement personalized skin care, aiming to reduce the incidence of moderate-to-severe acute radiation dermatitis in patients undergoing radiotherapy for breast cancer.

### Key Points

- First, this study analyzed patients with breast cancer who received the same radiotherapy dose and modality to explore the influencing factors of developing moderate-to-severe ARD in patients with breast cancer.
- Second, a nomogram prediction model was constructed to provide clinical staff with an objective and simple evaluation tool for the early and accurate identification of high-risk patients.
- Third, this study provides a reference for the prevention, evaluation, and management of moderate-to-severe ARD in breast cancer.

## Availability of Data and Materials

Data are available upon reasonable request to the corresponding author.

## Author Contributions

LC, NC, JW, XCZ, YNP, BZ and TTH all made substantial contributions to the conception and scope of the article, along with the acquisition and analysis of data. NC drafted the manuscript. All authors contributed to the important editorial changes in the manuscript. All authors read and approved the final manuscript. All

authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

## Ethics Approval and Consent to Participate

This study was approved by the ethics committee of the Affiliated Cancer Hospital of Xinjiang Medical University (K-2022035). This retrospective study was conducted in accordance with the latest edition of the National Postgraduate School of Health (Declaration of Helsinki), and all data were anonymized. Informed consent was waived by the Ethics Committee of the Affiliated Cancer Hospital of Xinjiang Medical University.

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## Conflict of Interest

The authors declare no conflict of interest.

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