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ORIGINAL RESEARCH

Analysis of Risk Factors for Progression of Breast Cancer-Related Lymphedema from the Reversible to Irreversible Stage: A Single-Center Retrospective Case-Control Study

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Objective: To explore the risk factors contributing to the transition from reversible to irreversible breast cancer-related lymphedema (BCRL), and to identify factors associated with irreversible BCRL.

Methods: A retrospective analysis was conducted on the demographic and disease-related data of 77 BCRL patients who underwent combined breast cancer surgery, axillary lymph node dissection, and adjuvant chemotherapy in a lymphedema specialty clinic of a hospital in Shantou from January 2022 to December 2024. According to the International Lymphedema Society staging, BCRL was divided into reversible (stages 0 and 1) and irreversible (stages 2 and 3) groups. Univariate analysis was used to identify the influencing factors for progression of BCRL from the reversible stage to the irreversible stage. Due to complete separation phenomena between certain independent variables and the outcome variable, no multivariate analysis was performed.

Results: The reversible group and irreversible BCRL groups of patients accounted for 31.2% and 68.8%, respectively. Univariate analysis showed that radiotherapy (P=0.049) and axillary web syndrome (P=0.028) were responsible for progression of BCRL.

Conclusion: Among breast cancer patients who underwent combined breast cancer surgery, axillary lymph node dissection (ALND), and adjuvant chemotherapy, followed by radiotherapy and development of axillary web syndrome are high-risk factors correlated with irreversible BCRL. Clinically, clinicians should conduct regular long-term monitoring and timely comprehensive intervention for patients with the above risk factors in the early stage of lymphedema, so as to effectively slow disease progression and avoid irreversible lymphatic injury. Nevertheless, this study is limited by its single-center retrospective design and lack of long-term follow-up data. Multi-center prospective cohort studies are needed in the future to further verify our findings and formulate more standardized whole-cycle management schemes for BCRL.

Keywords: breast cancer-related lymphedema, risk factor, progression

Introduction

Breast cancer predominantly affects women, accounting for approximately 90% of all cases and standing as the second most prevalent cancer globally. The prognosis for breast cancer is generally positive, as evidenced by five-year relative survival rates surpassing 80% for female patients in most regions, and these survival rates are on an upward trajectory, indicating improvements in treatment and early detection.[1] Despite this encouraging outlook, a significant concern arises from the fact that about 20% of women who undergo surgical treatment for breast cancer (BC) develop breast cancer-related lymphedema (BCRL), and research shows that the incidence of BCRL can vary widely, ranging from 15.5% to as

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high as 54% among those affected.[2] BCRL is characterized by swelling areas such as the arm, breast, and chest wall on the side where the breast cancer was treated, and this condition results from damage to the lymphatic system, which plays a crucial role in fluid balance and immune function.[3] The most common symptom of BCRL is physical impairment, especially in the upper limb, and involves a reduction in range of motion, muscle weakness, and abnormal sensations, and these symptoms are often accompanied by psychological distress, including feelings of depression and anxiety, and BCRL can lead to challenges in social interactions, familial relationships, occupational responsibilities, and sexual health, and economic strain and time commitments.[4]

The lymphatic system can be compromised due to various factors, including the cancer itself, surgical procedures, radiation therapy, trauma, or infections.[5] Patients with invasive breast cancer are more likely to undergo surgical interventions such as tissue sampling or complete removal of lymph nodes.[6] The incidence of BCRL two years after breast resection varies depending on the type of breast resection: 5.69% for those undergoing only partial breast resection, 7.31% for those having total breast resection, 5.96% for those undergoing lymph node biopsy, and 7.83% for those undergoing axillary lymph node dissection (ALND).[7] Karlsson et al indicate that for female breast cancer patients who undergo ALND and breast cancer surgery, the risk of lymphedema has been increasing.[8] Thus, when both breast resection and lymph node dissection are performed, the incidence of BCRL is the highest. Previous studies showed that ALND is the strongest risk factor for BCRL, being responsible for 30% to 50% of BCRL cases.[9,10]

Chemotherapy has been identified as a significant risk factor for the BCRL in patients who have undergo ALND. This risk is present regardless of whether the chemotherapy is administered as a neoadjuvant treatment prior to surgery or as a postoperative intervention. Jia et al emphasize that neoadjuvant chemotherapy acts as an independent risk factor for BCRL among patients undergoing ALND.[11] In contrast, Jinbo et al provided further insights, suggesting that the combined effects of postoperative chemotherapy, ALND, and a high body mass index (BMI) can substantially heighten the risk of developing BCRL.[12] Consequently, the focus of this study centers on female breast cancer patients who have undergone breast cancer surgery, ALND, and chemotherapy.

To effectively assess the severity of BCRL, this research adopted the International Society of Lymphology (ISL) grading system for BCRL, which categorizes the condition into four distinct stages: 0, I, II and III.[13] Stage 0 refers to a latency phase or subclinical condition where any discernible swelling is not yet apparent. During this stage, lymph transport may be compromised, resulting in subtle changes in tissue fluid composition and presenting with altered subjective symptoms. This phase can be transient, lasting for several months or even years. In Stage II, the changes become more pronounced, leading to structural alterations in the affected limb where elevating the limb rarely alleviates tissue swelling, and pitting edema becomes evident. As Stage II progresses, the ability to pit decreases due to the accumulation of excess subcutaneous fat and the development of fibrosis. Stage III is characterized by lymphostatic elephantiasis, where pitting may be absent, accompanied by trophic skin changes that can include acanthosis, modifications in skin's texture and thickness, further fat deposition fibrosis, and the formation of warty over-growths.

Lymphedema typically manifests in two distinct phases. The early reversible stage presents with extracellular fluid accumulation without dermal fibrosis, corresponding to subclinical or mild lymphedema. With disease advancement, irreversible intradermal fibrosis develops, transitioning to permanent chronic lymphedema.[14] In this study, BCRL in stage 0 and stage I is classified as reversible, while lymphedema in stage II and stage III is classified as irreversible. Early postoperative limb swelling is generally induced by surgical trauma, inflammation, local fluid accumulation or transient lymphatic drainage disturbance, which is reversible and temporary, distinct from persistent lymphedema triggered by structural damage to the lymphatic system.[14] Therefore, only patients with BCRL diagnosed more than 3 months after surgery were enrolled in the present study.

The expert consensus on integrated management of secondary limb lymphedema in 2025 states that secondary limb lymphedema is difficult to cure, its treatment methods include non-surgical treatment, such as comprehensive decongestive therapy, intermittent pneumatic compression, bandaging therapy, postural and lifestyle intervention, and traditional Chinese medicine treatment, as well as surgical treatments such as lymphaticovenous anastomosis, vascularized lymph node transfer, liposuction, and procedures focused on resection and volume reduction. For patients with ISL stage I or mild lymphedema symptoms, conservative treatment or single surgical treatment based on the main lesion is

recommended for "liquid" secondary limb lymphedema mainly characterized by lymph fluid accumulation, physiological surgical treatment is recommended.[15]

At the same time, research indicates that the more severe the lymphedema, the poorer the quality of life (QoL) of patients with BCRL.[3] Therefore, the severity of BCRL determines the treatment method and the difficulty of the treatment. Preventing and controlling the risk factors of patients, with stage 0 and stage I BCRL, will prevent the further deterioration of BCRL and reduce the difficulty of treatment. Comparing clinical parameters between reversible and irreversible BCRL to screen relevant associated factors facilitates early intervention, avoids progression to irreversible lymphedema, and improves patients' QoL.

Methods

Subjects and methods

This retrospective case-control study was conducted on 77 BCRL patients who underwent breast cancer surgery and ALND in the lymphedema specialist nursing clinic of the Cancer Hospital of Shantou University Medical College from January 2022 to December 2024. We did not formulate a dedicated prospective research protocol beforehand. All data were extracted retrospectively from archived clinical records for statistical analysis.

Ethical Approval and Informed Consent

This study was approved by the Ethics Committee of the Cancer Hospital of Shantou University Medical College (2024021), and filed in the national medical research filing information system. Each participant in this study was fully informed about the purpose of the research and the usage of the data, and they voluntarily and explicitly expressed their consent to use these data for this study. This study complies with the Declaration of Helsinki.

Inclusion and Exclusion Criteria

This study collected data for participants aged ≥18 years, diagnosed with breast cancer and BCRL, received both breast cancer surgery and ALND, received adjuvant chemotherapy, including preoperative or postoperative chemotherapy, at least 3 months after the surgery; and received comprehensive decongestive therapy at this research center. Exclusion criteria included preoperative upper limb edema, congenital lymphedema or other causes leading to lymphatic return disorders; and concurrent severe functional impairments of important organs such as the heart, liver and kidneys.

Sample Size and Power Calculations

This was an unmatched retrospective case-control study. Sample size was estimated based on results from a preliminary pilot study, with age as the primary exposure. The calculation was performed using the Fleiss formula for case-control studies:[16]

$$n = \frac{\left(Z_{\alpha/2}\sqrt{2\bar{p}(1-\bar{p})} + Z_{\beta}\sqrt{p_0(1-p_0)+p_1(1-p_1)}\right)^2}{(p_1-p_0)^2}$$

where

p0 = prevalence of age ≥60 years in the reversible group;

p1 = prevalence of age ≥60 years in the irreversible group;

$\bar{p}$ = (p0+p1)/2;

two-sided α = 0.05 ($Z_{\alpha/2}$ = 1.96);

power = 80% (Z_{β} = 0.84).

According to the pilot data, the prevalence of age ≥60 years was 0% in the reversible group and 37.5% in the irreversible group. The calculated minimum required sample size was 16 participants per group. Given the strict inclusion/exclusion criteria and homogeneous study population, a total of 24 patients in the reversible group and 53 in the irreversible group were enrolled, which met the calculated requirements and ensured adequate statistical power for the primary analysis.

Data Collection

The following data were collected through case review and face-to-face interviews, and all data were retrieved and analyzed anonymously. Data contained demographic information and disease-related factors, such as age, marital status, diagnosis, radiotherapy, BMI, number of children, educational level, employment status, the degree of housework undertaken, clinical stage, tumor classification, the time (years) from surgery to discovery of BCRL, hypertension, diabetes, surgical procedure, metabolic diseases, and axillary web syndrome. All BCRL assessments in this study were performed by professionally trained nurses with specialized certification in lymphedema. The nurses comprehensively judged and staged BCRL by integrating patients' medical history, physical signs, clinical symptoms and auxiliary examination results in accordance with the ISL staging criteria. The classification method of lymphedema was based on the lymphedema stages proposed by ISL and Rafn et al BCRL was divided into a reversible group and irreversible group.

Data Management and Analysis

For study purposes, all data were anonymized and treated in accordance with data protection laws and ethical research guidelines. Data of this study was collected by lymphedema therapists, and the person in charge of this study was responsible for supervising the data collection process and saving the data. Data saving and entry were done on the same day when possible.

SPSS Statistics 25.0 software was used to analyze all data. All independent variables were transformed into categorical variables. Categorical data were presented as counts and percentages, and the chi-square test was used for comparison between groups. Fisher's exact test was used for the theoretical frequencies of enumerated data below 5. Statistical significance was defined as a P value no greater than 0.05, while P values ranging from 0.05 to 0.10 indicated a marginal trend of difference. Due to the complete separation between some independent variables and the outcome variable, conventional binary logistic regression cannot provide stable estimates of the effects. Therefore, this study only reports the results of univariate analysis and did not conduct multivariate logistic regression analysis.

Results

A total of 77 patients diagnosed with BCRL were enrolled in this research. The average age of the cohort was 53.84 ± 9.22 years, with an age span from 36 to 72 years. Twenty-four patients were classified into the reversible lymphedema subgroup and 53 patients into the irreversible subgroup. The reversible group and the irreversible group of BCRL patients accounted for 31.17% and 68.83%, respectively.

The chi-squared test alongside Fisher's exact test served as the analytical approaches for univariate analysis comparison in this research. The univariate analysis showed that the variables with marginal statistically significant included radiotherapy, marital status, diabetes, and axillary web syndrome ($P < 0.1$) (Table 1). Further analysis confirmed that radiotherapy ($X^2 = 3.883$, $P = 0.049$) and axillary web syndrome (Fisher's exact test $P = 0.028$) were significantly associated with irreversible BCRL, indicating that these two factors are key risk contributors to the progression of reversible BCRL to irreversible status.

Table 1 The Results of Univariate Analysis of Reversible Group and Irreversible Group

Variable		Reversible Group	Irreversible Group	Chi-Square Test		Fisher's Exact Test	
				Value	P	Value	P
Age				0.887	0.346		
	18–59	18(23.4)	34(44.2)				
	≥60	6(7.8)	19(24.7)				
Marital status				3.269	0.071		
	Other	6(7.8)	5(6.5)				
	Married	18(23.4)	48(62.3)				

(*Continued*)

Table 1 (Continued).

Variable		Reversible Group	Irreversible Group	Chi-Square Test		Fisher's Exact Test	
				Value	P	Value	P
Diagnosis				0.012	0.913		
	Left breast cancer	11(14.3)	25(32.5)				
	Right breast cancer	13(16.9)	28(36.4)				
Radiotherapy				3.883	0.049		
	No	9(11.7)	9(11.7)				
	Yes	15(19.5)	44(57.1)				
BMI						2.761	0.493
	<18.5	0	1(1.3)				
	18.5–23.9	18(23.4)	30(39.0)				
	24–27.9	4(5.2)	17(22.1)				
	≥28	2(2.6)	5(6.5)				
Number of children						1.907	0.426
	0	2(2.6)	1(1.3)				
	1	4(5.2)	9(11.7)				
	≥2	18(23.4)	43(55.8)				
Educational level						5.791	0.205
	Illiterate	4(5.2)	6(7.8)				
	Primary school	11(14.3)	17(22.1)				
	Junior	3(3.9)	19(24.7)				
	Senior	3(3.9)	3(3.9)				
	College	3(3.9)	8(10.4)				
Employment status						3.373	0.184
	No	10(13.0)	33(42.9)				
	Full-time job	13(16.9)	17(22.1)				
	Part-time job	1(1.3)	3(3.9)				
The degree of undertake the housework						1.166	0.831
	A little bit	1(1.3)	3(3.9)				
	Somewhat	11(14.3)	28(36.4)				
	Quite a bit	7(9.1)	10(13.0)				
	All	5(6.5)	12(15.6)				
Clinical stage						0.679	0.842
	I	0	1(1.3)				
	II	18(23.4)	41(53.2)				
	III	6(7.8)	11(14.3)				
Tumor classification						3.511	0.302
	Triple-negative	3(3.9)	1(1.3)				
	Luminal A	2(2.6)	6(7.8)				
	Luminal B	16(20.8)	39(50.6)				
	Her-2 overexpression	3(3.9)	7(9.1)				
The time from surgery to BCRL (year)						2.120	0.599
	<1	15(19.5)	25(32.5)				
	1–3	7(9.1)	17(22.1)				
	4–6	2(2.6)	8(10.4)				
	≥7	0	3(3.9)				
Hypertension						-	0.423
	No	23(29.9)	46(59.7)				
	Yes	1(1.3)	7(9.1)				
Diabetes						-	0.092
	No	24(31.2)	46(59.7)				
	Yes	0	7(9.1)				

(*Continued*)

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Table 1 (Continued).

Variable		Reversible Group	Irreversible Group	Chi-Square Test		Fisher's Exact Test	
				Value	P	Value	P
Surgical procedure						3.716	0.142
	Breast-conserving therapy + ALND	2(2.6)	14(18.2)				
	Modified radical mastectomy + ALND	6(7.8)	8(10.4)				
	Total mastectomy + ALND	16(20.8)	31(40.3)				
Metabolic diseases						-	0.053
	No	23(29.9)	41(53.2)				
	Yes	1(1.3)	12(15.6)				
Axillary web syndrome						-	0.028
	No	21(27.3)	53(68.8)				
	Yes	3(3.9)	0				

Discussion

For breast cancer survivors suffering from postoperative BCRL, the hazard level of this complication rises in line with its severity.[17] At the same time, expert consensus on integrated management of secondary limb lymphedema has pointed that the treatment plan should be determined based on the stage of lymphedema, with the more severe the lymphedema, the more complex and difficult the treatment.[15] However, for decades, clinical practice has been guided by measures to reduce the risk of BCRL for individuals at risk of BCRL and those who have been diagnosed with BCRL, and many of these measures are based on experience.[18] Current studies lack sufficient evidence comparing clinical correlates between reversible and irreversible BCRL, restricting our understanding of variables predisposing patients to advanced permanent lymphedema. Accordingly, this study aimed to identify factors associated with irreversible BCRL versus reversible BCRL. Clarifying these correlates can support targeted clinical interventions to curb disease worsening, lower treatment burdens, and optimize long-term patient outcomes.

Existing literature has explored the risk factors for BCRL, but several studies have not limited the stage and surgical type of BCRL patients, and the research subjects were highly variable. Jinbo et al, identified risk factors for BCRL, including ALND, mastectomy, aggressive axillary procedures, postoperative radiotherapy, adjuvant chemotherapy, age and BMI.[12] However, the study focused on the risk factors for all stages of BCRL patients, without exploring the risk factors for progression in patients at different stages of BCRL. A meta-analysis on the risks of BCRL among Chinese female populations indicated that factors such as age over 40 years, BMI exceeding 24 kg/m^2, hypertension, positive lymph node metastasis, undergoing ALND, more than 15 lymph nodes dissected, postoperative complications, chemotherapy and radiotherapy could elevate BCRL risks.[19] However, this study was conducted on all types of breast cancer patients and did not further subdivide the types of surgeries, and the risk and risk factors for BCRL occurrence vary among breast cancer patients who undergo different types of surgeries. Therefore, to clarify the indicators associated with irreversible BCRL relative to reversible BCRL, rigorous definition of study participants is essential.

At the same time, early postoperative limb swelling was usually caused by surgical trauma, inflammation, local fluid accumulation or short-term lymphatic return disorder, which is a reversible and temporary phenomenon rather than a persistent lymphedema resulting from structural damage to the lymphatic system.[14] If temporary edema, which is usually in stage 0 or stage I, is included in the analysis of risk factors for the progression of BCRL, it will significantly overestimate the true incidence of reversible BCRL and interfere with the identification of risk factors. Ren et al have reported that the overall incidence rate of BCRL reaches 6.8% 5 months after the diagnosis of breast cancer, 19.9% 2 years after diagnosis, and 23.8% 7 years after diagnosis.[4] Thus, lymphedema typically progresses gradually. Setting the starting point of the research after the postoperative recovery period is helpful in focusing on persistent lymphedema. Other studies did not distinguish the onset time of the disease in BCRL patients, resulting in high research heterogeneity and inability to accurately reflect the risk factors of chronic progressive BCRL.

This study was strictly limited to patients who underwent dissection surgery after operation, and excluded those patients with lymphedema within 3 months after breast cancer surgery, focusing on chronic progressive patients, and concentrating on analyzing the risk factors for their progression to an irreversible stage. This study fills the research gap in existing research and provides an evidence-based references for clinical early screening of high-risk BCRL patients as well as targeted stratified intervention.

This study did not conduct a multivariate logistic regression analysis. The main reason for this was that some independent variables were completely separated from the outcome variable, making conventional regression analysis unable to accurately estimate the effects. The univariate results showed that radiotherapy and axillary web syndrome are statistically significant correlated with irreversible BCRL compared with reversible BCRL, but their independent effects on the progression of BCRL needs to be further verified after a larger sample size becomes available. *Medical Statistics* has stated that when data is completely separated or contains zero values in cells, the maximum likelihood estimation of the conventional logistic regression cannot converge, and one should avoid forcibly conducting multi-factor analysis, instead preferring to use single-factor analysis, precise logistic regression, or other alternative methods.[20]

This study suggests for breast cancer patients who underwent breast cancer surgery, ALND and adjuvant chemotherapy, if they were combined with radiotherapy and axillary web syndrome, they should be regarded as high-risk individuals for progression to irreversible BCRL. Clinically, clinicians should conduct regular long-term monitoring and timely comprehensive intervention for patients with the above risk factors in the early stage of lymphedema, so as to effectively slow disease progression and avoid irreversible lymphatic injury. This study is limited by a single center, small sample size, and retrospective design. Future studies need to be conducted in multiple centers, with a larger sample size, as well as a prospective cohort study to more comprehensively include potential confounding factors to further identify the independent predictors of irreversible progression of BCRL, and provide stronger evidence-based medical evidence for the formulation of individualized secondary prevention strategies.

Most studies have confirmed that radiotherapy is a risk factor for the occurrence of BCRL, but no study has explored whether radiotherapy is a risk factor associated with irreversible BCRL versus reversible BCRL. For example, Spiegel et al pointed out that regional lymph node irradiation can increase the risk of BCRL.[21] Kim et al indicated that radiation dose is positively correlated with risk of BCRL, and compared with patients who received the standard dose of low-fractionated regional lymph node irradiation, those who received an increasing dose of low-fractionated regional lymph node irradiation have faced elevated risk of developing lymphedema alongside shoulder dysfunction.[22] Our results of the single-factor analysis in this study suggest that patients with BCRL who have received radiotherapy have a higher risk of the disease progressing to an irreversible stage. However, this study does not explore the impact of specific radiotherapy parameters on disease progression. Future research should focus on aspects such as the local dose of radiotherapy and the radiotherapy site.

Skin problems could serve as a predictive factor for the aggravation of BCRL. Hunley et al, has indicated that cellulitis is a well-recognized important risk factor for and for exacerbation of BCRL, and it can be changed through preventive skin care.[18] However, in this study, none of the BCRL patients had suffered from cellulitis. Therefore, we could not investigate the impact of cellulitis on the progression of BCRL. A previous study indicated that current evidence does not determine whether axillary web syndrome poses a risk of BCRL, but that axillary web syndrome should be regarded as a potential risk factor for BCRL.[23] In this study, through the results of single-factor analysis showed that patients who had undergone breast cancer surgery and ALND, and developed lymphedema along with axillary web syndrome within 3 months might progress to irreversible lymphedema. This suggests that axillary web syndrome is a potential risk factor for the irreversible BCRL. Furthermore, Zhu et al indicated that excessive scoping of ALND and a larger number of lymph node dissections can cause significant trauma to the lymphatic transportation network and blood vessels in the upper limbs and chest of breast cancer patients, damaging the compensatory function of lymphatic vessels and resulting in lymphatic reflux disorders on the surgical side, leading to the occurrence of BCRL.[19]

The subjects included in this study were all patients who underwent ALND. Due to the fact that the previous surgical history of the subjects included in this study came from several different medical institutions, and the number of ALND for some patients was not specified in their cases, it was relatively difficult for us to obtain this data. Therefore, in this study, we did not include the indicator of the scope of ALND. The next study will try to include all the subjects with

complete medical records. Since this study aims to explore the risk factors for reversible and irreversible BCRL, the subjects are relatively rare and the results are quite valuable. However, our next study will pay more attention to this point.

The main limitations of this study are the relatively small sample size, and the sparse distribution of certain predictor variables, which restricts the effectiveness of multivariate analysis. Additionally, due to the difficulty in obtaining the study sample, this research could only conduct studies on patients who visited the lymphedema specialist outpatient clinic of our unit. The breast and axillary lymph node surgeries experienced by the patients in this study came from different medical institutions and different doctors, making it difficult to obtain the patient's previous surgical history. Therefore, disease-related factors, such as the lack of data on the extent of ALND, could not be fully and adequately included in this study. Furthermore, there are relatively few studies that focus on the risk factors influencing progression of BCRL-related diseases. Therefore, the references we have consulted are rather limited. Future multi-center studies are needed to obtain a larger sample size and be able to correctly obtain complete disease-related information of the patients, so as to explore the risk factors for progression of BCRL from the reversible stage to the irreversible stage.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work. Zebing Luo, Manjia Xu, Weijie Gao and Qiongshan Chen contributed equally to this work.

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Disclosure

The authors have no conflicts of interest to disclose.

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