Int. j. adv. multidisc. res. stud. 2026; 6(6):71-76

Received: 10-09-2026
Accepted: 20-10-2026

International Journal of Advanced Multidisciplinary Research and Studies

ISSN: 2583-049X

Comparative Early Toxicities of Hypofractionated Versus Conventional Adjuvant Radiotherapy in Patients with Early Breast Cancer After Mastectomy

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DOI: https://doi.org/10.62225/2583049X.2026.6.6.7103
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Abstract

Background: Hypofractionated radiotherapy reduces treatment duration compared with conventional radiotherapy. However, evaluating early treatment-related toxicity is essential, particularly in resource-constrained settings.

Objective: To compare early treatment-related toxicities between hypofractionated and conventional adjuvant radiotherapy in post-mastectomy patients with breast cancer.

Methods: This prospective quasi-experimental study was conducted at the National Institute of Cancer Research and Hospital, Dhaka, from June 2013 to May 2014. Sixty patients with stage IIB ductal carcinoma were enrolled. Thirty received hypofractionated radiotherapy (40 Gy in 15 fractions over 3 weeks), while 30 received conventional radiotherapy (50 Gy in 25 fractions). Hematological, skin, pulmonary, and cardiac toxicities were assessed weekly during treatment and monthly for three follow-up visits using established toxicity grading criteria.

Results: No statistically significant differences in hematological or skin toxicities were observed between groups during treatment ($p > 0.05$). Skin toxicities were predominantly grade 0 or 1. Pulmonary and cardiac toxicities remained grade 0 in all patients during the assessed early treatment periods. At the first follow-up, grade 0 hematological toxicity was observed in 28 patients receiving hypofractionated radiotherapy versus 24 receiving conventional radiotherapy. Follow-up toxicity differences were not statistically significant ($p > 0.05$).

Conclusion: Hypofractionated radiotherapy demonstrated a comparable early toxicity profile to conventional radiotherapy in post-mastectomy patients with stage IIB breast cancer. Its shorter treatment duration may reduce patient burden and optimize radiotherapy resource utilization in resource-constrained settings.

Keywords: Breast Cancer, Hypofractionated Radiotherapy, Conventional Radiotherapy, Acute Toxicity, Radiation Toxicity

Introduction

Breast cancer is one of the most important malignant diseases affecting women and represents a significant public health problem in Bangladesh. Breast carcinoma most commonly originates from the epithelial lining of the mammary ducts or lobules, with ductal carcinoma accounting for the majority of cases. The development of breast cancer is associated with a number of hormonal, reproductive, genetic, familial and lifestyle-related risk factors [1].

Available institutional data from the National Institute of Cancer Research & Hospital (NICRH) demonstrated the substantial burden of breast cancer among women attending the institution. During the period from January 2008 to December 2010, breast carcinoma was reported as the most common cancer among female patients attending NICRH and the second most common cancer overall, with a considerable proportion of patients belonging to the 35–54-year age group [2]. This emphasizes the importance of developing effective and practical treatment strategies for breast cancer in the Bangladeshi setting.

Established risk factors include increasing age, dietary and lifestyle factors, smoking exposure, alcohol consumption, obesity and family history. Genetic susceptibility, particularly mutations involving BRCA1 and BRCA2, also contributes substantially to breast cancer risk [3-6]. Histologically, breast cancer comprises several subtypes, with invasive ductal carcinoma being the

predominant form. Tumour differentiation and histological characteristics are important determinants of prognosis and treatment planning [7].

Patients with breast cancer may present with a breast lump, changes in breast size or contour, nipple retraction or other nipple abnormalities, breast pain and axillary swelling. Advanced local disease may result in skin ulceration, pain, bleeding and infection, while regional lymphatic involvement can lead to upper-limb edema and other complications. Early identification and appropriate treatment are therefore essential to minimize disease progression and improve clinical outcomes.

The treatment of early breast cancer is multidisciplinary. Depending on the stage and pathological characteristics, treatment may include surgery, radiotherapy, chemotherapy and hormonal therapy. In Bangladesh, mastectomy is frequently performed, and postoperative radiotherapy is used when indicated to improve locoregional disease control. Radiotherapy has consequently become an integral component of adjuvant management for selected patients with breast cancer.

Although radiotherapy provides important therapeutic benefits, normal tissues within or adjacent to the treatment field may receive radiation exposure and develop treatment-related toxicities. Acute or early toxicities may involve the skin, hematological system, lungs and, depending on the treatment field and dose distribution, the heart. The severity of these effects may influence patient comfort, treatment compliance and quality of life.

Conventional adjuvant radiotherapy has traditionally consisted of approximately 50 Gy delivered in 25 fractions of 2 Gy per fraction over 5–6 weeks. This schedule requires repeated hospital attendance and prolonged treatment exposure. In addition to the inconvenience to patients, prolonged treatment courses can increase the burden on radiotherapy facilities, which is particularly relevant in resource-limited settings.

Hypofractionated radiotherapy provides a higher dose per fraction while reducing the total number of treatment sessions. The biological rationale for this approach is supported by evidence suggesting that breast carcinoma may have a fractionation sensitivity that permits the use of moderately larger fraction sizes. Clinical trials have reported comparable tumour control and radiation morbidity between appropriately selected hypofractionated and conventional schedules [8].

Nevertheless, the use of larger fraction sizes has raised an important clinical consideration regarding the tolerance of normal tissues. Skin and subcutaneous tissues, lung, heart and other structures within the radiation field may potentially be affected by changes in fraction size. Therefore, assessment of acute toxicity is essential when evaluating a shortened radiotherapy regimen, particularly in patients receiving post-mastectomy irradiation.

A reduction in the overall treatment time would have considerable practical advantages if it can be achieved without increasing treatment-related toxicity. Patients could complete adjuvant radiotherapy in fewer visits, potentially reducing travel-related expenses, treatment interruption and the overall burden on both patients and radiotherapy services. This may be especially valuable in Bangladesh, where access to radiotherapy facilities remains an important consideration.

Despite the increasing interest in hypofractionated radiotherapy, assessment of its acute toxicity profile in the local patient population is important because treatment practices, patient characteristics and available radiotherapy resources may differ between settings. Comparative evaluation of treatment-related toxicities can therefore provide clinically useful evidence regarding the safety and tolerability of a shortened treatment schedule.

The present study was conducted to compare early treatment-related toxicities between hypofractionated and conventional adjuvant radiotherapy in patients with early breast cancer following mastectomy. Particular attention was given to hematological, skin, pulmonary and cardiac toxicities during and after treatment. The findings were intended to determine whether hypofractionated radiotherapy could reduce treatment duration without producing a clinically significant increase in early radiation-related toxicity.

Materials and Methods

Study Design and Setting

This prospective quasi-experimental study was conducted at the National Institute of Cancer Research and Hospital (NICRH), Mohakhali, Dhaka, Bangladesh, between June 2013 and May 2014. The study was designed to compare the frequency and severity of early treatment-related toxicities between hypofractionated and conventional adjuvant radiotherapy in patients with stage IIB breast cancer following mastectomy.

Study Population and Sampling

The study included 60 post-mastectomy patients with histopathologically confirmed ductal carcinoma of the breast. Patients were recruited using a purposive sampling technique. Although the calculated sample size was 98, a total of 60 patients were enrolled because of time constraints. Participants were assigned to two treatment groups, with 30 patients in each arm.

Patients were eligible if they had stage IIB breast cancer, were aged ≤70 years, had a Karnofsky Performance Status (KPS) >70, and demonstrated adequate hematological, hepatic, and renal function. Patients with non-ductal histology, distant metastases, recurrent disease, previous radiotherapy or chemotherapy, KPS <70, age >70 years, synchronous multiple malignancies, cervical lymph node involvement from an unknown primary, or major dysfunction of vital organs were excluded. Only patients who fulfilled the eligibility criteria and provided written informed consent were enrolled.

Radiotherapy Protocol

Patients were divided into two treatment groups according to the radiotherapy schedule. Patients in Arm A received hypofractionated radiotherapy at a prescribed dose of 2.66 Gy per fraction, administered five fractions per week, to a total dose of 40 Gy in 15 fractions over three weeks. Patients in Arm B received conventional radiotherapy at 2 Gy per fraction, administered five fractions per week, to a total dose of 50 Gy in 25 fractions over five weeks. Both treatment groups underwent two-dimensional radiotherapy planning, and irradiation was delivered using a linear accelerator.

Pretreatment Evaluation and Data Collection

Before initiating radiotherapy, all patients underwent a

detailed clinical assessment, including medical history and physical examination. Baseline investigations included complete blood count, liver and renal function tests, serum electrolytes, chest radiography, and ultrasonography of the whole abdomen. Computed tomography of the chest and upper abdomen and isotope bone scanning were performed when clinically indicated. Clinical and treatment-related information was collected using a pretested semi-structured questionnaire and hospital medical records.

Outcome Measures and Toxicity Assessment

The primary outcome was the frequency and severity of early treatment-related toxicities during radiotherapy and subsequent follow-up. The evaluated toxicities included hematological, skin, pulmonary, and cardiac adverse effects. Patients were assessed weekly throughout radiotherapy using clinical examination and laboratory investigations, including complete blood count, platelet count, and serum creatinine measurement. Treatment-related toxicities were evaluated using the Common Terminology Criteria for Adverse Events (CTCAE), version 4.0 (2010), together with World Health Organization (WHO) recommendations for grading acute and subacute toxicity. Toxicity grades were recorded at each assessment to evaluate their frequency and severity in both treatment groups.

Follow-up Assessment

Following completion of radiotherapy, patients were scheduled for three monthly follow-up visits. During each visit, clinical assessments were performed, and hematological, skin, pulmonary, and cardiac toxicities were documented. Symptomatic supportive treatment, including analgesics and antihistamines, was provided when clinically indicated. The frequency and severity of treatment-related toxicities during treatment and follow-up were compared between the two radiotherapy groups.

Statistical Analysis

Data were compiled in a master chart, checked for completeness and consistency, and analyzed using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as mean ± standard deviation (SD), while categorical variables were expressed as frequencies and percentages. Student's t-test was used to compare continuous variables between the two groups. Categorical variables, including treatment-related toxicity grades, were compared using the chi-square test or Fisher's exact test, as appropriate. All statistical tests were two-sided, and a p-value <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Ethics Committee of the National Institute of Cancer Research and Hospital, Dhaka, Bangladesh. Before enrollment, participants were informed about the study objectives, procedures, potential risks, and expected benefits in an understandable local language. Written informed consent was obtained from all participants. Patient identities, clinical information, and medical records were kept confidential throughout the study.

Result

Table 1: Distribution of the patients by oral tobacco use

Oral tobacco use	Category of treatment		χ^2	p-value*
	Hypofraction (Arm A)	Conventional (Arm B)		
Yes	9 (30.0)	10 (33.3)	1.011	0.304
No	21 (70.0)	20 (67.7)		
Total	30 (100.0)	30 (100.0)		

* Fisher's Exact Test

In arm A 9 patients had history of oral tobacco use (30%), while in arm B 10 patients had history of oral tobacco use (33.3%). No statistical significance was found between these two groups (p = 0.304).

Table 2: Distribution of the patients by other personal habits

Personal habits	Category of treatment		χ^2	p-value*
	Hypofraction (Arm A)	Conventional (Arm B)		
Oral pill use				
Yes	8 (26.7)	6 (20.0)	.093	1.00
No	22 (73.3)	24 (80.0)		
Betel leaf & nut consumption				
Yes	10 (33.3)	5 (16.7)	.944	1.00
No	20 (67.7)	25 (83.3)		

* Fisher's Exact Test

In arm A 10 patients used to consume betel leaf & nut (33.3%), while in arm B 5 patients were betel leaf and nut consumers (16.7%). In contrast, the numbers of oral pill users were less in the both groups. No statistical significance were found between these two groups (p>0.05).

Table 3: Distribution of the patients by family history of breast cancer

Family history of breast cancer	Category of treatment		χ^2	p-value*
	Hypofraction (Arm A)	Conventional (Arm B)		
No	28 (93.3)	29 (96.7)	1.451	0.980
Yes	2 (6.7)	1 (3.3)		
Total	30 (100.0)	30 (100.0)		

* Fisher's Exact Test

Table 3 shows the distribution of the patients by family history of breast cancer. Most of the patients did not give such history of cancer. Only 2 (6.7%) patients in arm A had family members with breast cancer. Only one patient in arm B patients (3.3%) had such history. However, no statistical significance was observed (p=0.980).

Table 4: Distribution of the patients by hematological toxicity during treatment

Hematological toxicity during treatment		Hypofraction (Arm A)		Conventional (Arm B)		*p*-value
		n	%	n	%	
1st week	Grade 0	30	100.0	30	100.0	-
2nd week	Grade 0	30	100.0	28	93.3	0.492*
	Grade 1	0	0.0	2	6.7	
3rd week	Grade 0	30	100.0	24	80.0	0.024*
	Grade 1	0	0.0	6	20.0	
4th week	Grade 0	NA	NA	28	93.3	-
	Grade 1	NA	NA	2	6.7	
5th week	Grade 0	NA	NA	26	86.7	-
	Grade 1	NA	NA	4	13.3	

* Fisher's Exact Test; NA= Not applicable

Hematological toxicity is compared in three different periods of time. At the end of the 1st week of the treatment there were thirty grade 0 toxicities in both arm A & in arm B.

After 2nd week of treatment there were thirty grade 0 toxicities in arm A while in arm B there were 28 grad 0 & 2 grade 1 toxicities. This difference was not statistically significant also (p=0.492).

At the end of the 3rd week of the treatment there were thirty grade 0 toxicities in arm A in contrast to twenty-four grade 0 toxicities and six grade 1 toxicities in arm B. This difference was statistically significant (p = 0.024).

At the end of the 4th week of the treatment there were twenty-eight grade 0 toxicities and two grade 1 toxicities in arm B. After 5th week of the treatment there were twenty-six grade 0 toxicities and four grade 1 toxicities in arm B.

Table 5: Distribution of the patients by skin toxicities during treatment

Skin toxicities during treatment		Hypofraction (Arm A)		Conventional (Arm B)		*p*-value
		n	%	n	%	
1st week	Grade 0	30	100.0	30	100.0	-
2nd week	Grade 0	30	100.0	29	96.7	1.000
	Grade 1	0	0.0	1	3.3	
3rd week	Grade 0	30	100.0	26	86.7	0.112
	Grade 1	0	0.0	4	13.3	
4th week	Grade 0	NA	NA	21	70.0	-
	Grade 1	NA	NA	9	30.0	
5th week	Grade 0	NA	NA	21	70.0	-
	Grade 1	NA	NA	8	26.7	
	Grade 2	NA	NA	1	3.3	

NA= Not applicable

Skin toxicity is compared in three different periods of time in the above table. At the end of the 1st of the treatment all the patients in both arms showed grade 0 toxicity.

At the end of the 2nd week of the treatment there were thirty grade 0 toxicities in arm A. There were twenty-nine grade 0 toxicities and one grade 1 toxicity in arm B. This difference was not statistically significant (p = 1.000).

At the end of the 3rd week of the treatment there were thirty grade 0 toxicities in arm A in contrast to twenty-six grade 0 toxicities and four grade 1 toxicities in arm B. This difference was not statistically significant (p = 0.112).

At the end of the 4th week of the treatment there twenty-one grade 0 toxicities and nine grade 1 toxicities.

After 5th week of the treatment there were twenty-one grade 0 toxicities, eight grade 1 toxicities and one grade 2 toxicity in arm B.

Table 6: Distribution of the patients by lung toxicity during treatment

Lung toxicity during treatment		Hypofraction (Arm A)		Conventional (Arm B)	
		n	%	n	%
1st week	Grade 0	30	100.0	30	100.0
2nd week	Grade 0	30	100.0	30	100.0
3rd week	Grade 0	30	100.0	30	100.0
4th week	Grade 0	NA	NA	30	100.0
5th week	Grade 0	NA	NA	28	93.3
	Grade 1	NA	NA	2	6.7

* Fisher's Exact Test; NA= Not applicable

Lung toxicity is compared in three different periods of time in the above table. At the end of the 1st, 2nd and 3rd weeks of the treatment all the patients in both arms showed grade 0 toxicity while at the end of the 4th weeks of treatment all the patients in arm B showed grade 0 toxicity.

After 5th week of the treatment there were twenty-eight grade 0 toxicities, and two grade 1 toxicities in arm B.

Discussion

The safety of a hypofractionated radiotherapy schedule depends not only on maintaining tumour control but also on avoiding an unacceptable increase in radiation-induced toxicity. In the present study, acute hematological, skin, pulmonary and cardiac toxicities were evaluated during treatment and during follow-up in patients receiving hypofractionated and conventional radiotherapy.

Hematological toxicity was assessed at different time points during treatment. Up to the third week, no statistically significant difference was observed between the two treatment groups (p>0.05). At the first follow-up, 28 patients in the hypofractionated group had grade 0 hematological toxicity, while two had grade 1 toxicity and none had grade 2 toxicity. In the conventional group, 24 patients had grade 0 toxicity, five had grade 1 toxicity and one had grade 2 toxicity. Although there appeared to be a numerical difference in the distribution of grades, the overall difference between the treatment groups was not statistically significant.

Skin toxicity was similarly evaluated at different points during treatment. Patients in both treatment groups predominantly demonstrated grade 0 and grade 1 skin toxicity, and no statistically significant difference was observed between the two arms (p>0.05). These findings are consistent with the observations of Bentzen *et al* [9]. and Yarnold *et al*. [10], who reported no significant difference in skin toxicity between conventional and hypofractionated treatment schedules.

Pulmonary toxicity was also minimal during the treatment period. At the end of the first, second and third weeks, all patients in both treatment groups showed grade 0 pulmonary toxicity. At the fourth week, patients in the conventional treatment group also showed grade 0 pulmonary toxicity. Thus, no clinically important difference in pulmonary toxicity was identified between the two schedules. These findings are consistent with reports by Whelan *et al*. [11] and Fujii *et al*. [12], who found no significant difference in pulmonary toxicity between conventional and hypofractionated radiotherapy.

Cardiac toxicity was assessed in a similar manner. At the end of the first, second and third weeks of treatment, all patients in both groups showed grade 0 cardiac toxicity. At the fourth week, all patients in the conventional group continued to demonstrate grade 0 toxicity. The absence of clinically evident early cardiac toxicity in either group suggests that neither treatment schedule produced a detectable acute cardiac adverse effect during the observation period. However, the relatively short follow-up limits conclusions regarding late cardiac effects.

At the first follow-up assessment, skin toxicity remained broadly comparable between the two groups. Pulmonary and cardiac assessments showed grade 0 toxicity in all patients. Ultrasonography of the whole abdomen was normal in all patients in the hypofractionated group, while 28 patients in the conventional group had normal findings and two had abnormal findings. Overall, the differences in follow-up toxicities between the two treatment groups were not statistically significant ($p>0.05$).

The findings of the present study are in agreement with previous evidence supporting the tolerability of moderate hypofractionation. The START A trial, which randomized 2236 patients from 17 centres across the United Kingdom, demonstrated comparable locoregional tumour control and treatment-related toxicity between conventional and hypofractionated treatment schedules [13]. Bentzen *et al*. [9] and Yarnold *et al*. [10] similarly reported no significant increase in skin toxicity with hypofractionated treatment. These findings support the view that appropriately selected hypofractionated schedules can be administered without a clinically significant increase in acute toxicity.

The biological rationale for this observation is related to the fractionation sensitivity of breast carcinoma and surrounding normal tissues. Armpilia *et al*. [14] discussed the potential for breast carcinoma to have a fractionation response that allows the use of larger doses per fraction while maintaining acceptable tolerance of dose-limiting normal tissues, including the skin, subcutaneous tissue, muscle and ribs [14].

The practical significance of the present findings is particularly relevant in a resource-limited setting. The hypofractionated schedule reduced the treatment course from 25 fractions over approximately 5 weeks to 15 fractions over 3 weeks. If this reduction can be achieved without an increase in acute toxicity, patients can complete treatment with fewer hospital visits and reduced treatment-related inconvenience, while radiotherapy departments may improve patient turnover.

Overall, the present study found no statistically significant difference in hematological, skin, pulmonary or cardiac toxicities between hypofractionated and conventional radiotherapy during treatment and early follow-up. These findings suggest that the hypofractionated regimen was well tolerated in the study population. Nevertheless, the small sample size and limited follow-up are important limitations. In particular, the absence of significant early cardiac or pulmonary toxicity cannot be interpreted as evidence of absence of late radiation effects. Longer-term follow-up and larger studies are necessary to adequately evaluate late toxicity and establish the long-term safety profile of hypofractionated post-mastectomy radiotherapy.

Conclusion

Hypofractionated radiotherapy was well tolerated, with no statistically significant difference in early hematological, skin, pulmonary or cardiac toxicities compared with conventional radiotherapy. The shorter 3-week treatment schedule can reduce the number of hospital visits while maintaining an acceptable early toxicity profile. This approach may be particularly advantageous in Bangladesh, where radiotherapy facilities are limited and patient waiting lists are substantial. Hypofractionation therefore represents a practical and potentially cost-effective alternative for selected patients requiring adjuvant breast radiotherapy.

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