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Original Research Article

Comparative clinical response and tumour control following hypofractionated versus conventional adjuvant radiotherapy in early breast cancer after mastectomy

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ABSTRACT

Background: Adjuvant radiotherapy is an established component of early breast cancer treatment. Conventional radiotherapy requires several weeks, whereas hypofractionation shortens treatment while potentially maintaining tumour control. This study compared the clinical response and short-term tumour control achieved with hypofractionated and conventional adjuvant radiotherapy after mastectomy in early breast cancer.
Methods: A 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 histopathologically confirmed ductal carcinoma and stage IIB disease were enrolled by purposive sampling and divided into two groups of 30. Arm A received 40 Gy in 15 fractions over 3 weeks, and Arm B received 50 Gy in 25 fractions. Response was assessed using RECIST criteria, with monthly follow-up for three visits.
Results: The mean age was 39.7±6.788 years in the hypofractionated group and 41.07±8.196 years in the conventional group. All patients had stage IIB disease, and tumour grade was comparable between groups (p=0.214). Complete clinical response occurred in 29 of 30 patients (96.7%) in each group, and no local recurrence was observed in either group.
Conclusions: Hypofractionated adjuvant radiotherapy provided clinical response and short-term local control comparable to conventional radiotherapy. Reducing treatment from 25 to 15 fractions may be a practical alternative for selected patients, particularly where prolonged radiotherapy burdens patients and treatment facilities.

Keywords: Breast cancer, Hypofractionated radiotherapy, Conventional radiotherapy, Tumour control, Clinical response, Mastectomy

INTRODUCTION

Breast cancer is a malignant neoplasm arising from the epithelial tissues of the breast, most commonly from the epithelial lining of the mammary ducts and less frequently, from the lobular structures. Ductal carcinoma constitutes the majority of breast carcinomas, while lobular carcinoma represents another important histological subtype. Breast cancer is a major health problem among women worldwide and is an increasingly important cause of morbidity and mortality in developing countries. Several reproductive and hormonal factors associated with prolonged exposure to endogenous estrogen have been implicated in increasing the lifetime risk of breast cancer.

These include early menarche, late menopause, nulliparity, delayed first childbirth and lack of breastfeeding.[1] In Bangladesh, although population-based epidemiological data on breast cancer remain limited, an institution-based cancer registry at the National Institute of Cancer Research & Hospital (NICRH) during 2008–2010 identified breast carcinoma as the most common cancer among female patients attending the institution and the second most common cancer overall. The largest proportion of patients belonged to the 35–54-year age group.[2]

The risk of breast cancer is influenced by several demographic, lifestyle, genetic and familial factors. Increasing age, dietary factors, exposure to tobacco smoke, alcohol consumption, obesity and a family history of breast cancer have all been associated with increased risk. In addition, inherited mutations involving the BRCA1 and BRCA2 genes are important genetic risk factors for breast cancer.[3-6] The disease encompasses several histological subtypes, among which invasive ductal carcinoma is the predominant form. Histological grade also provides important information regarding tumor differentiation and biological behaviour.[7] The clinical presentation of breast cancer varies according to the stage and biological characteristics of the disease.

A breast lump is the most common presenting feature, while changes in breast size or contour, nipple retraction, breast pain and axillary swelling may also occur. With progressive local and regional disease, ulceration, pain, bleeding, infection, lymphatic obstruction and upper-limb edema may develop. Early diagnosis and appropriate staging are therefore essential for selecting optimal treatment and improving disease control. Management of early breast cancer requires a multidisciplinary approach involving surgery, radiotherapy and, when indicated, systemic treatment such as chemotherapy and endocrine therapy. Treatment selection depends on disease stage, tumour size, histological characteristics, lymph-node involvement, age and performance status.

In Bangladesh, total mastectomy remains a commonly practiced surgical approach, followed by adjuvant treatment according to the pathological and clinical characteristics of the disease. Radiotherapy plays an important role in achieving locoregional control in patients with early breast cancer who require adjuvant irradiation. Conventional radiotherapy has traditionally used approximately 50 Gy delivered in 25 fractions of 2 Gy over 5–6 weeks. However, this prolonged treatment schedule may create considerable logistical and financial burdens for patients, particularly in resource-constrained settings. Hypofractionated radiotherapy involves delivery of a somewhat higher dose per fraction over a reduced number of treatment sessions.

The rationale for hypofractionation in breast cancer is based partly on the observation that breast tumour tissue may have a fractionation sensitivity that permits larger fraction sizes while maintaining effective tumour control. Clinical studies and randomized trials have demonstrated that appropriately selected hypofractionated schedules can provide comparable local control and acceptable morbidity compared with conventional fractionation.8 Reduction in overall treatment time may also have practical and biological advantages. Prolonged radiotherapy treatment can increase the opportunity for tumour cell repopulation, which may adversely influence treatment effectiveness. A shorter treatment schedule may therefore provide an attractive alternative when adequate tumour control can be achieved without an unacceptable increase in treatment-related complications.

For patients in Bangladesh, particularly those receiving treatment at high-volume cancer centres, reducing the number of hospital visits may improve treatment convenience, reduce indirect costs and allow more efficient utilization of limited radiotherapy facilities. Therefore, evaluating whether hypofractionated radiotherapy can achieve tumour control comparable to conventional fractionation is clinically relevant.

Therefore, this study aimed to compare the clinical response and tumour control achieved with hypofractionated and conventional adjuvant radiotherapy among patients with early breast cancer following mastectomy, and to determine whether reducing the overall treatment time through hypofractionation could provide therapeutic effectiveness comparable to the conventional radiotherapy schedule.

METHODS

This prospective quasi-experimental study was conducted in the radiotherapy outpatient department of the National Institute of Cancer Research and Hospital, Mohakhali, Dhaka, from June 2013 to May 2014. Post-mastectomy patients with histopathologically proven duct cell carcinoma of the breast who fulfilled the selection criteria were selected. The sample size was determined using the formula $n = [p_1(1 - p_1) + p_2(1 - p_2)] / (p_1 - p_2)^2 \times (z_\alpha + z_\beta)^2$, where p_1 and p_2 are the proportions of patients developing the outcome in the two arms, z_α is the Z value (two-tailed) at the chosen level of significance (1.96 at the 5% level) and z_β is the Z value (one-tailed) at the chosen power (1.64 at 95% power). Based on other studies,9,11 p_1 and p_2 were assumed to be around 10% and 30%, respectively (p_1=0.10; p_2=0.30; z_α=1.96; z_β=1.64).

The calculated sample size was 98, but because of time constraints the study was limited to 60 patients. Patients were included if they had histopathologically diagnosed duct cell carcinoma of the breast; early breast carcinoma, stage IIB, after mastectomy; a Karnofsky performance status of more than 70; an age of 70 years or younger; and minimum laboratory values of hemoglobin more than 11 gm/dl or >60%, an absolute WBC count of 4000 cells/ml or more, a platelet count of 100,000 cells/ml or more, bilirubin of 1 mg/dl or less, an AST level not more than four times the upper limit of normal and a serum creatinine

level of 1.5 mg/dl or less. Patients were excluded if they had histology other than duct cell carcinoma; distant metastases on clinical and radiographic examination; previous treatment, including prior radiotherapy or chemotherapy; Karnofsky performance status below 70; age over 70 years; synchronous multiple malignancies; recurrent disease; a neck node from an unknown primary; or other major vital organ dysfunction. Purposive sampling was used, in which patients were selected through these inclusion and exclusion criteria, and those who gave informed written consent were finally enrolled.

Hypofractionated radiotherapy (arm A) was defined as five fractions per week at 2.66 Gy per fraction, to a total dose of 40 Gy in 15 fractions over 3 weeks, and conventional radiotherapy (arm B) as five fractions per week at 2 Gy per fraction, to a total dose of 50 Gy in 25 fractions, delivered on a linear accelerator.

A semi-structured questionnaire containing the patient profile was prepared and pre-tested, and data were collected over about one year by interviewing and examining the patients and from their reports and hospital documents; each interview usually lasted about an hour, and detailed histories were taken from all selected patients. The research protocol was approved by the ethical committee of the National Institute of Cancer Research and Hospital before the study began.

The objectives, procedure, alternative methods, risks and benefits were explained to the patients in easily understandable local language, informed written consent was obtained, and patients were assured that all information and records would be kept confidential.

After cleaning and editing, the data were compiled on a master chart and analysed using SPSS for Windows (IBM SPSS Statistics for Windows, version 19.0, Armonk, NY, IBM Corp.). Continuous data were expressed as mean±SD and compared using Student's t test. Categorical data were expressed as number and percentage and compared using the chi-squared and Fisher's exact tests. A two-tailed $p<0.05$ was considered significant.

RESULTS

This quasi experimental study was carried out to compare the treatment responses between hypofractionated and conventional radiotherapy in early breast cancer at NICRH, Dhaka. Total study population was 60 among which 30 were in intervention arm (arm A, hypofractionated radiotherapy) and 30 were in the control arm (arm B, conventional radiotherapy).

Figure 1 shows the age distribution of the early breast cancer patients. The mean age of the conventional group was 41.07 (SD±8.196) years and that of the intervention group was 39.7 (SD±6.788) years. No significant difference was observed between these two groups (t=-0.703 (df =56.056) p=0.485).

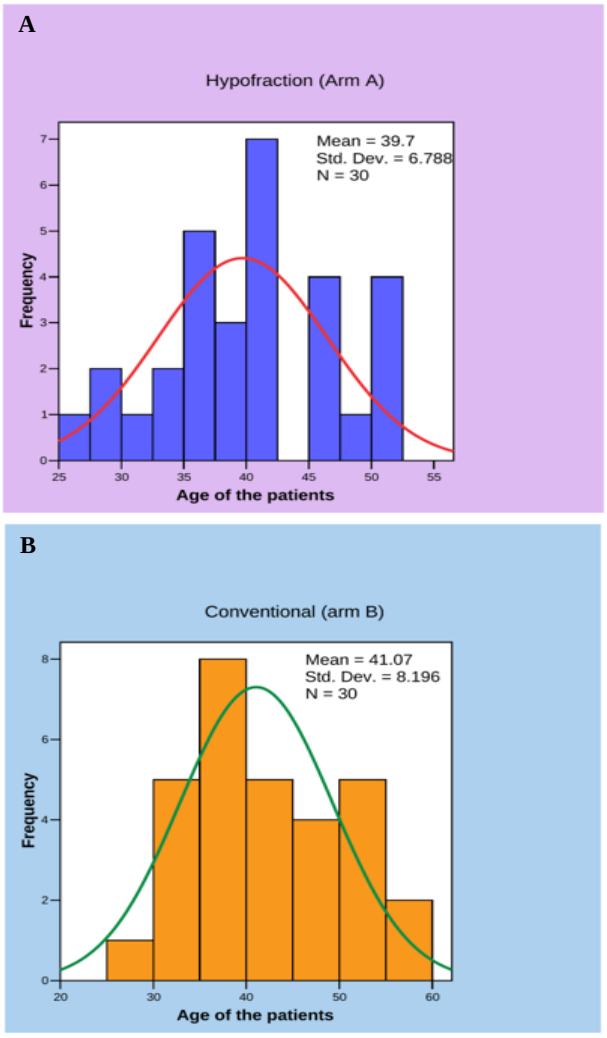


Figure 1 (A-B): Age distribution of the patients.

A total of 30 patients of early breast cancer were included in arm A of the study. They were divided into three age groups. Age ranged from 25 to 52 years. Maximum numbers (19, 63.3 %) were found in the age group of 41-50 years. The results are shown in the Table 1.

A total of 30 patients of early breast cancer were included in arm B of the study. They were divided into three age groups. Their age ranged from 28 to 56 years. Half of the patients in arm B (15, 50.0 %) were found in the age group of 41-50 years. The results are shown in the Table 2.

Table 3 shows the distribution of the patients by occupation. Most of the patients in both arms were housewives (80% in arm A and 73.4% in arm B). Seven patients (23.3%) in arm B were service person. No, statistically significant difference was observed regarding occupation between these two groups (p=0.128) (Table 3).

Table 4 shows the level of education of the patients. Most of the patients in both arms were literate to various degrees. One-third patients in arm A and one tenth patients in arm B had below SSC level education. The respondents

in arm B had higher level of education than that of the arm A. This difference was statistically significant (p=0.002) (Table 4). Table 5 shows marital statuses of the patients. Most of the patients in both arms were married. Only two patients in arm B were unmarried. The difference was not statistically significant (p=0.320) (Table 5). Most of the patients in both arms were Muslims (in arm A 86.7% and in arm B 83.3%). Among other religious believes hinduism is notable. More than 13% of all the patients were Hindu (Table 6).

Table 1: Age distribution of the arm A patients (n=30).

Age group (in years)	Frequency	Percent	Mean (±SD) (yrs)	Range (yrs)
≤40	19	63.3	39.7 (6.788)	25 – 52
41-50	10	33.3		
>50	1	3.3		
Total	30	100.0		

Table 2: Age distribution of the arm B patients (n=30).

Age group (in years)	Frequency	Percent	Mean (±SD) (yrs)	Range (yrs)
≤40	15	50.0	41.07 (8.196)	28 – 56
41-50	11	36.7		
>50	4	13.3		
Total	30	100.0		

Table 3: Distribution of the patients by occupation (n=60).

Occupation	Category of treatment		χ^2	P value (Fisher's Exact Test)
	Hypofraction (Arm A)	**Conventional (Arm B)**		
Housewife	24 (80.0)	22 (73.4)	5.687	.128
Service	3 (10.0)	7 (23.3)		
Business	0 (0.0)	1 (3.3)		
Others	3 (10.0)	0 (0.0)		
Total	30 (100.0)	30 (100.0)		

Table 4: Distribution of the patients by education (n=60).

Educational attainment	Category of treatment		χ^2	P value
	Hypofraction (Arm A)	**Conventional (Arm B)**		
Illiterate	9 (30.0)	4 (13.3)	18.989	0.002
Below SSC	10 (33.3)	3 (10.0)		
SSC	8 (26.7)	4 (13.3)		
HSC	2 (6.7)	8 (26.7)		
Graduate	1 (3.3)	11 (36.7)		
Total	30 (100.0)	30 (100.0)		

Table 5: Distribution of the patients by marital status (n=60).

Marital status	Category of treatment		χ^2	P value
	Hypofraction (Arm A)	**Conventional (Arm B)**		
Married	28 (93.3)	24 (80.0)	3.508	0.320
Unmarried	0 (0.0)	2 (6.7)		
Widowed	2 (6.7)	3 (10.0)		
Divorced	0 (0.0)	1 (3.3)		
Total	30 (100.0)	30 (100.0)		

Table 6: Distribution of the patients by religion (n=60).

Religion	Category of treatment		χ^2	P value (Fisher's Exact Test)
	Hypofraction (Arm A)	Conventional (Arm B)		
Islam	26 (86.7)	25 (83.4)	1.020	0.601
Hinduism	4 (13.3)	4 (13.3)		
Christianity	0 (0.0)	1 (3.3)		
Total	30 (100.0)	30 (100.0)		

DISCUSSION

Radiotherapy is an established component of the multidisciplinary management of early breast carcinoma. Conventional adjuvant radiotherapy has traditionally been delivered at a dose of 50 Gy in 25 fractions of 2 Gy over approximately 5 weeks. Although effective, this prolonged treatment schedule requires frequent hospital attendance and places a considerable burden on patients and healthcare services.[9,10] A shorter radiotherapy schedule may therefore provide an important practical advantage if comparable tumour control can be maintained.

The present quasi-experimental study was conducted at the National Institute of Cancer Research and Hospital (NICRH) to compare the clinical effectiveness of hypofractionated and conventional adjuvant radiotherapy in patients with early breast cancer following mastectomy. Sixty patients were included, with 30 patients receiving hypofractionated radiotherapy and 30 receiving conventional radiotherapy. The hypofractionated group received 40 Gy in 15 fractions of 2.66 Gy over 3 weeks, whereas the conventional group received 50 Gy in 25 fractions of 2 Gy. The baseline characteristics of the two treatment groups were broadly comparable. The mean age was 39.7±6.788 years in the hypofractionated group and 41.07±8.196 years in the conventional group. Most participants in both groups were housewives, married and Muslim. No, statistically significant difference was observed between the groups with respect to these demographic characteristics ($p>0.05$).

The distribution of disease characteristics was also comparable. All patients in both groups were classified as stage IIB disease. Histological grading showed no statistically significant difference between the groups ($p=0.214$). In the hypofractionated group, 6.7% of tumours were well differentiated, 30% were moderately differentiated and 63.3% were poorly differentiated, compared with 6.7%, 23% and 70%, respectively, in the conventional group.

The rationale for hypofractionation is based on the radiobiological characteristics of breast carcinoma and the potential for breast cancer to have a fractionation sensitivity that permits the use of larger doses per fraction. Armpilia et al discussed the biological basis of hypofractionation and noted that breast carcinoma may have a fractionation response different from that of squamous carcinomas.[11] This provides a rationale for investigating shorter fractionation schedules while maintaining effective tumour control. The present study demonstrated comparable clinical outcomes between the two treatment groups. Complete clinical response was observed in 29 of 30 patients (96.7%) in both the hypofractionated and conventional radiotherapy groups. Furthermore, none of the patients in either arm developed local recurrence during the follow-up period. These findings suggest that the reduction in overall treatment time achieved with the hypofractionated regimen did not compromise short-term clinical response or observed local disease control.

The absence of local recurrence in either treatment group is consistent with reports from several international studies. Clinical reports from different centres have demonstrated broadly equivalent outcomes between shorter and conventional radiotherapy schedules.[12–22] A well-known Canadian randomized trial compared conventional radiotherapy of 50 Gy in 25 fractions with a hypofractionated schedule of 42.5 Gy in 16 fractions over 22 days in women with node-negative early breast cancer and demonstrated equivalent treatment outcomes.[16] The updated results remained supportive of equivalent outcomes after 10 years of follow-up.[13]

El-Sayed and Abdel-Wanis also evaluated overall survival, disease-free survival, locoregional control and treatment-related toxicity among breast cancer patients treated with conventional and hypofractionated schedules.[12] With a median follow-up of 42 months, the 4-year overall survival and disease-free survival rates for the whole study population were 86.5% and 83.8%, respectively. Their analysis did not demonstrate a significant difference in overall survival according to fractionation schedule ($p=0.12$, HR 0.63, 95% CI: 0.35–1.34). They concluded that hypofractionated radiotherapy was safe and resulted in outcomes comparable to conventional fractionation.[23] A Japanese study also reported broadly similar local control and toxicity outcomes using shorter fractionation schedules of 42.5–

47.8 Gy in 16–20 fractions, although the median follow-up was 26 months. Similarly, an Italian study involving 539 patients reported only 1.8% breast relapse (10/539) at the time of analysis, with no nodal recurrence involving the supraclavicular, axillary or internal mammary nodes.[22] These findings are broadly consistent with the absence of local recurrence observed in the present study.

The findings of the present study therefore support the clinical feasibility of hypofractionated adjuvant radiotherapy in selected patients with early breast cancer. The comparable complete response rate and absence of local recurrence in both treatment groups suggest that 40 Gy in 15 fractions over 3 weeks can provide short-term clinical control comparable to 50 Gy in 25 fractions. This reduction in treatment duration may be particularly valuable in resource-constrained settings, where repeated hospital visits can impose considerable financial and logistical difficulties on patients. However, the interpretation of local-control findings should take into account the small sample size and relatively short follow-up of the present study. The absence of local recurrence during the observation period does not establish long-term equivalence in recurrence-free or overall survival. Larger studies with prolonged follow-up would be required to determine the long-term oncological effectiveness of this hypofractionated schedule.

CONCLUSION

Hypofractionated radiotherapy demonstrated clinical tumour control comparable to conventional radiotherapy in patients with early breast cancer following mastectomy. Both treatment groups showed a high complete clinical response, and no local recurrence was observed during the follow-up period. These findings suggest that reducing the number of fractions did not compromise short-term tumour control. Therefore, hypofractionated radiotherapy may be considered an effective alternative to conventional fractionation in appropriately selected patients with early breast cancer.

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