

A Comparative Study of Conventional Radiotherapy and Hypofractionated Radiotherapy in Post Mastectomy Locally Advanced Breast Cancer Patients

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ABSTRACT

Background: There has been a growing trend toward hypofractionated radiotherapy (HFRT) over conventional fractionated radiotherapy (CFRT) for post mastectomy locally advanced breast cancer patients. CFRT is associated with lengthy hospitalization and longer waiting lists. However, HFRT has been studied in many countries and associated with less overall treatment time, more convenient for patients and health care providers, but there is no enough study conducted by Cobalt 60 machine. **Objectives:** The objective of this study was to evaluate and compare the safety and effectiveness of CFRT and HFRT in terms of locoregional control, response and toxicities of locally advanced post mastectomy breast cancer patients. **Methodology:** It was a quasi-experimental study. Study setting and period: Study was conducted by Cobalt 60 machine in the Department of Radiotherapy of Chittagong Medical College Hospital, Chittagong, for one-year period from July 2019 to June 2020. Participants and methods: Sixty-four previously untreated postmastectomy female patients with histologically proven duct cell carcinoma (stage IIIA, IIIB, IIIC) were randomized into CFRT (50 Gy in 25 fractions with 2 Gy per fraction) and HFRT (42.72 Gy in 16 fractions with 2.67 Gy per fraction) group with thirty-two patients falling in each group. After completion of radiotherapy they were followed up 8 weeklies for 6 months at the OPD. Treatment response and toxicities were assessed and compared between two groups. **Results:** Majority of the patients in both groups were less than 50 years of age. Both treatment groups were comparable in terms of local control, response and toxicities. Anorexia, nausea, vomiting, dermatitis and pneumonitis were the treatment toxicities in the present study. Grade I and Grade II were the most common grade for dermatitis, with only 1 patient in each group with Grade III dermatitis. There were 3 pneumonitis cases all were in grade I (2 in HFRT group and 1 in CFRT group). The site of distant metastasis was brain (3.1%), and lung (3.1%). None of the patient developed local recurrence in either of the two groups. Two deaths were reported in HFRT group till last follow-up. The locoregional outcome and survival were found to be comparable in both the groups. **Conclusion:** In our study, both control group (CFRT) and study group (HFRT) showed almost comparable results in term of locoregional control, response and toxicities. Hence, HFRT is not inferior to CFRT for postmastectomy breast cancer patients.

Keyword: Hypofractionated radiotherapy (HFRT), Conventional fractionated radiotherapy (CFRT), Breast cancer, Cobalt 60 machine.

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INTRODUCTION

Cancer is a growing problem globally. In 2001 about 10 million cases had been diagnosed as cancer annually with 6 million deaths [1]. These figures increased gradually thereafter and in 2018 there were estimated 18.1 million new cases and 9.6 million cancer deaths [2]. Among different malignancies, breast cancer is one of the most common malignancies in women worldwide and is the leading cancer-related cause of death in women [3]. In [4], it was estimated that 2,088,849 (11.6%) new cases of breast cancer were identified and 626,679 (6.6%) cases of death due to breast cancer in the world [2]. Breast cancer remains a leading dreadful cancer of women in Bangladesh. It has become a hidden burden which accounts 69% death of women. In Bangladesh the rate of breast cancer occurrence is estimated to be 22.5 per 100000 females of all ages. In case of Bangladeshi women, aged between 15-44 years, breast cancer has the highest prevalence 19.3 per 100000 compared to any other type of cancer [5]. National Institute of Cancer Research and Hospital in Bangladesh has demonstrated a steady increase of breast cancer in incidence. In Bangladesh, maternal mortality survey (2010) cited that breast cancer was responsible for 21% of death of women between 15-49 years of age. Regardless of variations of unavailable data, it is plainly observable that, breast cancer is fast becoming a major cause of concern [5,6,7]. There is no population based large-scale surveys or nationwide disease survey except some hospital-based study for breast cancer in Bangladesh [7]. Some regional surveys have indicated that the incidence of breast cancer is rising in Bangladeshi women [6]. However, most of these studies were focused on the patients attending in the oncology department of different tertiary level hospitals. Nearly 70% of Bangladeshi population located in rural areas. Due to lack of adequate awareness and adequate screening facilities and/or programme majority of patients of carcinoma breast come to the hospital for receiving treatment in locally advanced stage unlike the western world, so mastectomy is performed more often than breast conservative surgery (BCS) Most of these patients require postmastectomy radiotherapy (PMRT) to decrease locoregional recurrence [8-10]. PMRT is recommended in patients with 4 or more positive axillary lymph nodes (ALN) and should be strongly considered in patients with 1-3 positive ALN. In patients with negative nodes, PMRT is indicated for tumors more than 5 cm or positive/close pathological margins [11]. The normally used conventional fractionated chest wall radiotherapy (CFRT) uses 2 Gy daily fractions for 5 weeks. Most of the time patients discontinue treatment in between due to financial constraints, lack of family support, commuting to hospital which ultimately affects the treatment outcome. Bangladesh is a resource limited country and most of the health care settings are overburdened due to inadequate facilities with

respect to total population. So, such a long treatment schedule has major implications on both patient's compliance and department workload. There has been a growing trend toward hypofraction which involves delivering a higher dose per fraction for a shorter number of fractions for a biologically equivalent dose while maintaining the same toxicity and locoregional control rates. Many randomized trials [12-14] have confirmed the noninferiority results of hypofractionated RT (HFRT) in breast cancer patients after surgery. There are radiobiological reasons justifying the use of hypofractionation in breast carcinoma. The alpha/beta value for breast cancer has been estimated at 4 Gy, whereas the alpha/beta value for soft tissues of the breast is approximately 3.5 Gy [15]. Since breast cancer sensitivity to radiotherapy is similar to that of healthy tissues responding with late reactions, high fraction doses may be more efficient in destroying tumor cells. This short HFRT schedule using 2.67 Gy daily fractions for 3.1 weeks would be most convenient for patients, especially those coming from remote areas to the RT facilities in addition to health-care providers, as it would increase the turnover in the department without compromising the treatment outcome [16-22]. In this context, the present prospective study was carried out in the Department of Radiotherapy, CMCH, for one-year period, with an aim to compare the locoregional control, response, toxicities in postmastectomy breast cancer patients with CFRT versus HFRT.

OBJECTIVES

General Objective

- To evaluate and compare the safety and effectiveness of CFRT and HFRT in terms of locoregional control, response and toxicities of locally advanced post mastectomy breast cancer patients.

Specific Objectives

- To describe the demographic and clinical characteristics of the patients with respect to age, sex, risk factors and histological type.
- To compare the recurrence rate between two groups.
- To compare the grade and frequency of toxic effects by RTOG Acute Radiation Morbidity Criteria between two groups.

METHODOLOGY

This was Quasi-experimental study. The patients were selected purposively. A total of 64 patients were included in this study in two group, Group I CFRT: Conventional fractionated radiotherapy and group II HFRT: Hypofractionated

radiotherapy. The study was conducted in the Department of Radiotherapy, Chittagong Medical College Hospital, Chattogram, Bangladesh. At 1 July 2019 to 30 June 2020.

Inclusion Criteria

- Histopathologically diagnosed case of duct cell carcinoma of breast
- Postmastectomy patients with clinically and histopathologically locally advanced breast cancer (stage IIIA-IIIC).
- Patients of carcinoma breast without distant metastasis.
- All patients even if anyone received neoadjuvant or adjuvant chemotherapy.
- Female patients of any age.
- Patients are required to Karnofsky performance status >70.
- Minimum laboratory criteria required to include:
 - Hemoglobin should be more than 11 gm/dl or >60%
 - An absolute WBC count > 4000/mm³
 - Total platelet count > 1,00,000/ mm³
 - Bilirubin level of less than or equal to 1mg/dl.
 - An AST level not more than 2.5 times of the upper limit of normal.
 - A serum creatinine level of less than or equal to 1.5mg/dl.

Exclusion Criteria

- Distant metastasis proved by clinical imaging technique.
- Previously treated patient with radiotherapy.
- Existence of synchronous multiple malignancies.
- Recurrent cases.
- Other major vital organ dysfunction.
- Male patients of carcinoma breast.
- Eligible patients unwilling to participate in the study.
- Karnofsky performance status < 70.
- Poor LVEF less than 50%.

Data Processing and Analysis

Data were analyzed by SPSS version 23.0. Continuous data were expressed as mean (\pm SD) or median (IQR) and categorical data as frequency (percentage). Baseline characteristics and outcome variables were compared between groups either by independent sample t test, Mann-Whitney U test or by Chi-square test. A P value of <0.05 will be regarded as significant.

Ethical Implication

Ethical approval was taken before starting the study from the Ethical Review Committee of Chittagong Medical College. Informed written consent was taken from mother or concerned guardian. All measures were taken to preserve patient's anonymity and privacy.

RESULTS

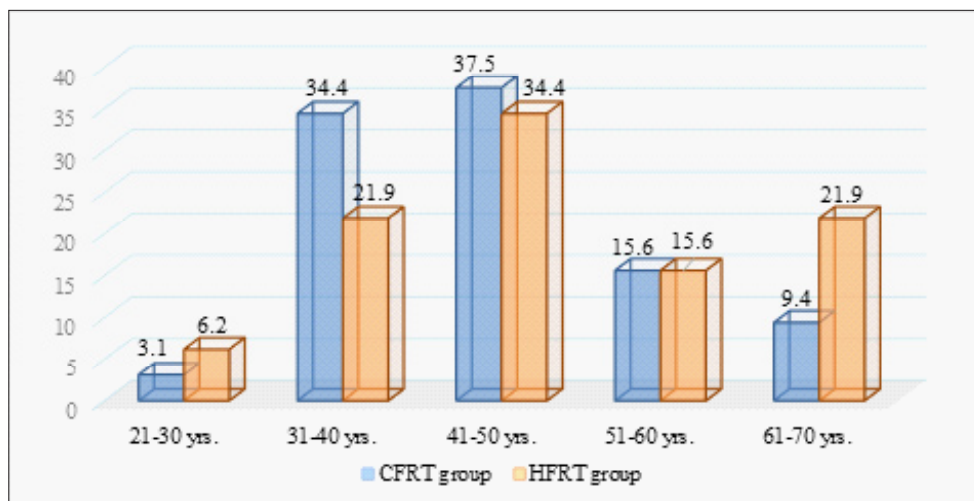


Figure 1: Age distribution of patients by treatment arms (N=64)

Figure 1 showed, overall the age range from 25-65 years. The majority of the patients in both treatment arms were in 41-

50 years range. The mean age of patients in the CF arm was slightly lower than that of the HF arm (47.2 vs 47.9 years).

Table 1. Comparison of monthly family income of the patients between two groups (N=64)

Economic status	CFRT (n=32) No. of patient (%)	HFRT (n=32) No. of patient (%)
Lower Class (≤ 10000)	15 (46.9%)	14 (43.8%)
Middle Class (> 10000 & < 20000)	10 (31.3%)	11 (34.4%)
Upper Class (≥ 20000)	7 (21.8%)	7 (21.8%)

Table I showed on the basis of monthly family income (MFI) the respondents were arbitrarily classified into three classes (MFI ≤ 10000 lower class; MFI > 10000 & < 20000 middle class; MFI ≥ 20000 upper class). It was seen that majority of the study subjects (arm A 46.9% vs. arm B 43.8%) were from lower economic class.

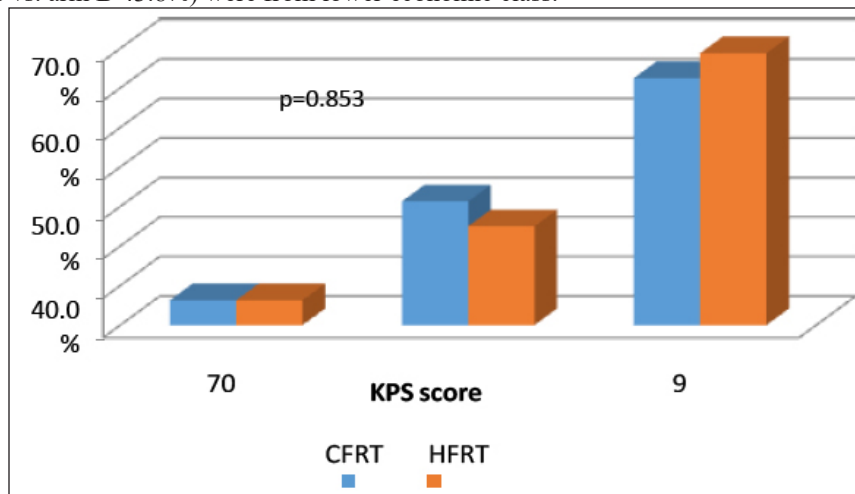


Figure 2: Distribution of the patients by performance status at the time of diagnosis between two Arms (N=64)

Figure 2 showed, Majority of the patients in both groups had KPS score of 90 and both groups were statistically similar in terms of KPS score ($p>0.05$)

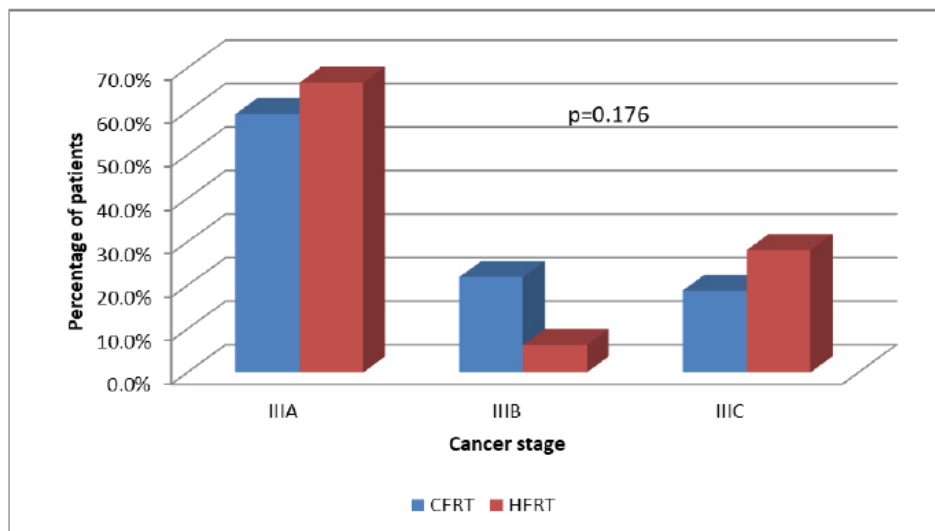


Figure 3: Comparison of cancer stage of the patients by their group (N=64)

Figure 3 showed according to the selection criteria, all the patients in the study had stage III A, stage IIIB, stage III In CFRT group, stage IIIA and IIIC tumors were more compared to HFRT group. However, both the groups were similar in terms of the tumor staging ($p>0.05$).

Table 2. Treatment history of the patients between two groups (N=64)

Characteristics	CFRT (n=32) No. of patients (%)	HFRT (n=32) No. of patients (%)	p value
Received adjuvant CT	14(43.8)	21(65.6)	0.132
Received neo-adjuvant CT	18(46.2)	11(34.4)	

Table II showed majority of the patients in HFRT group received adjuvant chemotherapy and in CFRT group received neo-adjuvant chemotherapy. It was not statistically significant ($p > 0.05$).

Table 3. Receptor status of the patients between two groups (N=64)

Characteristics	CFRT (n=32) No. of patients (%)	HFRT (n=32) No. of patients (%)	p value
ER ^{+ve} , PR ^{+ve} , HER-2 ^{-ve}	19(59.4)	18 (56.3)	0.132
ER ^{+ve} , PR ^{+ve} , HER-2 ^{+ve}	4(12.5)	3(9.4)	
ER ^{-ve} , PR ^{-ve} , HER-2 ^{+ve}	3(9.4)	6(18.6)	
ER ^{-ve} , PR ^{-ve} , HER-2 ^{-ve}	6(18.6)	5(15.6)	

Table III showed majority of the patients in both groups were ER^{+ve}, PR^{+ve}, HER-2^{-ve}. Triple negative breast cancer was 18.6% and 15.6% respectively in CFRT and HFRT group respectively. The distribution was similar in both groups ($p > 0.05$).

Table 4. Comparison of radiotherapy induced toxicities between the study arms (N=64)

Toxicities	CFRT (n=32) No. of patients (%)	HFRT (n=32) No. of patients (%)	P value
Anorexia	4(12.5)	3(9.4)	0.689
Nausea	3(9.4)	3(9.4)	1.0
Vomiting	2(6.3)	0(0)	0.584
Dermatitis			
Grade I	8(25.0)	9(28.1)	0.894
Grade II	4(12.5)	3(9.5)	
Grade III	1(3.1)	1(3.1)	
Pneumonia			
Grade I	1(3.1)	2(6.2)	0.874
Septicaemia	0(0)	1(3.1)	0.845
Treatment held	1(3.1)	1(3.1)	1.0

Table VI showed treatment toxicities were found to be comparable between the two groups ($p > 0.05$). Besides, anorexia, nausea and vomiting; dermatitis and pneumonitis were the treatment toxicities in the present study. Grade I and Grade II were the most common grade for dermatitis.

Table 5. Disease status at last follow up in patients by their study group (N=64)

Characteristics	CFRT (n=32) No. of patients (%)	HFRT (n=32) No. of patients (%)	p value
No evidence of disease	31 (98.8)	29 (90.6)	0.613
Local recurrence	0 (0)	0 (0)	NA
Regional recurrence	0 (0)	0 (0)	NA
Distant metastasis	1 (3.1)	1 (3.1)	1.0
Death	0 (0)	2 (6.2)	0.892

Table VI showed follow-up was of 6 months for entire group. Disease status in the form of local (chest wall) recurrence, regional (nodal) recurrence, distant metastasis, and no evidence of disease was documented as per the last follow-up (Table VII). The locoregional outcome and survival were found to be comparable in both the groups. The site of distant metastasis was brain (3.1%), and lung (3.1%). None of the patient developed second malignancy including cancer of the opposite breast. Two deaths were reported in HFRT group till last follow-up.

DISCUSSIONS

The present study was a single institution, hospital based, prospective, randomized trial comparing the effect of HFRT versus CFRT in postmastectomy locally advanced breast cancer patients. In many international studies it is an established fact that HFRT (42.72Gy 16 fractions over 3.1 weeks) protocols are as effective as the conventional radiotherapy (50 Gy in 25 fractions over 5weeks) [21,23,24,25]. In this study there was minimal radiation related complication. The short term outcomes of the present study are in consistence with several other studies. Regarding treatment related toxicities Grade I and Grade II were the most common grade for dermatitis. Grade I was the most common grade of acute radiation dermatitis in both the groups, with an incidence of 25% in CFRT group and 28.1% in HFRT group. Grade II acute dermatitis had an incidence of 12.5% in CFRT group and 9.5% in HFRT group. Only 1 patient in each group had grade III dermatitis. This was in agreement with what has been reported by Pinitpatcharalert et al., (2011) [25] as he reported 2% patients in CFRT group and 3% patient in HFRT group had GII dermatitis. Similar toxicities were reported by Pabitra et al. (2018) [23] where the incidence of Grade I dermatitis 75.5% vs 76.4%, Grade II dermatitis 20.7% vs 21.8%, Grade III dermatitis 3.8% vs 1.8% in CFRT and HFRT group respectively. The toxicity results of present study also comparable to the results of Dr. Ramesh et al. (2016) [24] which evaluated Grade II skin reactions in 28% patients in control arm and 8% in study arm, Grade III skin reactions were 13% in control arm vs 4% in study arm. However, this was much less than that reported by Rastogi et al. (2018) [22] as they reported more than half of their patients in both arms developed grade II dermatitis. Ali et al., (2014) [26] reported 24% incidence of Grade II dermatitis and resulted in only 1week treatment interruption compared with 9% in CF with 10 days interrupted treatment. Radiation pneumunitis, a well-known toxicity of chest walls. In present study regarding radiation induced pneumunitis, symptomatic radiation pneumunitis was found. Only three patients had pnemonitis and all of them were in Grade I. 3.1% in CFRT group and 6.2% in HFRT group had pneumunitis. These cases were settled with steroids and antibiotics. These findings were in agreement with Pinitpatcharalert et al., (2011)

and Rastogi et al., (2018). Shahid et al., (2009) [25,22,17] has reported a 5% and Shaaban et al., (2010) [27] 4.7% incidence of radiation pneumunitis with 40 Gy/15 fractions protocol. In contrast, Lind et al., (1998) [28] and Hanna et al., (2002) [29] reported that 9%-15% of patients had radiation pneumunitis. Lymphedema is an established complication of both ALN dissection and axillary RT, was not developed in any of the patient of my study. The study by El Sayed et al stated that hypofractionated radiation was safe and showed acceptable toxicity rate. Incidence of skin toxicity and radiation induced pneumunitis werecomparable between hypofractionated and conventional radiation arms. A previous study (Banu et al., 2015) [19] conducted in Bangladesh also demonstrated very few radiation related toxicities including patients (94%) had grade-I acute skin toxicity and only 3 patients (6%) developed grade-II acute skin toxicity. The incidents of the toxicity results were less in those studies conducted by Linear accelerator (LINAC) in comparison to the result of toxicity of the present study which was conducted by Cobalt 60. Because now a days LINAC is the machine of choice for radiotherapy as it is high energetic, provide more precise and accurate dose, has more penetrating power, less penumbra effect, less toxicity etc. in comparison to Cobalt 60. But as we have only one machine that is Cobalt 60, I had to conduct my study by Cobalt 60 and every patient was counseled and opted. Though the toxicities are more by Cobalt 60 but not that much. So we can use Cobalt 60 for radiotherapy where there is no other option. All patients tolerated radiotherapy well. Other than one patient in HFRT group all other patients completed postmastectomy radiation therapy. Treatment interruption was not significantly different among the two groups and was seen in 1 patient in CFRT group (7 days) and 1 patient inHFRT group (7 days). Follow-up period was of 6 months for entire group. At last follow-up, no patients had local recurrence in either of the two groups. Abhilash et al. (2016) [21] reported 6.7% local recurrence in both group. In my study one patient (3.1%) in CFRT had lung metastases and 1 patient (3.1%) in HFRT group developed brain metastasis. Abhilash et al. (2016) [21] reported 3.3% distant metastasis inCFRT group. The strength of the current study was prospective in nature and was almost even in distribution ofthe tumour and clinical characteristics in both the groups; it confirmed the feasibility of hypofractionated radiotherapy in postoperative breast cancer patients and comparability in terms of local control and toxicities.

CONCLUSION

In the current study, there is no significant difference between conventional radiotherapy and hypofractionated radiotherapy in terms of locoregional disease control, response and toxicities. With CFRT requires lengthy hospitalization or commuting to hospital for radiotherapy and is associated with higher costs and longer waiting lists. This may create a major obstacle

for patients with disabilities or those who cannot rely on their families" support and probability of missing radiotherapy is higher with older patients. On the other hand, HFRT with radiobiological advantage of overall shorter treatment time, have shown same response in terms of tumor control with the advantage of decreased workload, increased compliance and reduced cost of treatment. So hypofractionated radiotherapy may be an alternative treatment option for postmastectomy locally advanced breast cancer patients.

LIMITATIONS

There are some limitations in this study. These are mentioned below:

- The study was conducted in single tertiary level hospital of Bangladesh. As only one institution was involved in the study, the results may not be directly extrapolated to other patient populations.
- As we have no LINAC machine we had to conduct our study by Cobalt 60, though we know that LINAC is better than Cobalt 60 in many aspects e.g. high energetic, provide more precise and accurate dose, has more penetrating power, less penumbra effect, less toxicity etc.
- The major limitations of the present study are small number of patients and comparatively short period of follow-up.

RECOMMENDATIONS

Hypofractionated schedules can be considered as a reliable alternative in radiation treatment for post mastectomy breast cancer patients. Nevertheless, whether this ultimately transforms into comparable overall survival and disease free survival needs to be tested with multi-institutional randomized study with large number of patients and with longer follow-up.

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