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Observational Study for Effectiveness and Safety Profile Measurement for Treatment of Breast Cancer Using 3d-Crt V/S Imrt"

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Abstract: *Breast cancer is among the most common diagnoses found on daily female patient treatment lists at Regional Cancer Centre, Raipur. One of the primary treatment modalities prescribed for women diagnosed with breast cancer is radiotherapy. Radiotherapy has been demonstrated to lengthen survival time, to improve localized tumor control, and to reduce mortality. All these invaluable medical benefits are not without physical and psychological costs. From the physical perspective, breast cancer radiotherapy is most often related to fatigue and skin toxicity. Thus it becomes important at our part to understand what type of toxicity to expect from radiation for breast cancer while using different types of radiation techniques. The purpose of this study was to understand acute skin toxicity experienced during treatment and immediately after completion of radiation therapy for breast cancer.Our study reflects that skin toxicity is reported only bypatients treated under 3D-CRT technique. Around 18% patients reported skin toxicity between grade I to grade IV. Thus we conclude that IMRT is better technique to treat breast cancer patients as it provides maximum medical benefits with minimal physical and psychological costs as compare with 3D-CRT radiation technique.*

Key-words: ***C****ancer, Breast, Radiation, 3D-CRT, IMRT, Toxicity*

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I. Introduction

In patients with early breast cancer, local standard therapy is breast-conserving surgery (BCS) followed by radiotherapy to the whole breast or, in the case of high-risk patients after mastectomy, radiotherapy to the chest wall with or without drainage areas. The radiotherapy techniques in the treatment of breast cancer vary in different institutions but in general, the issue of radiation dose delivery to the chest wall after total mastectomy or to the breast following breast conservation surgery remains complex. In the conventional breast irradiation technique, the beam arrangement consists of two opposing tangential glancing portals, which allows acceptable coverage of the breast tissue while minimizing the dose to the adjacent critical structures (*i.e.*, ipsilateral lung, contralateral breast, and heart). Physical or dynamic wedges are usually added to these tangential beams in order to compensate for the rapid changes in external contours and to improve the dose uniformity to the entire breast.

The clinical benefit of RT in the treatment of BC must be balanced against the documented risk for early and late side-effects, including predominantly skin, pulmonary and cardiac toxicity. Nowadays, the risk for cardiac toxicity is amplified by the widespread and growing use of adjuvant systemic chemotherapy and targeted therapies. However, most data on radiation-induced damage after long latency periods (15-20 years) come from old series that applied obsolete RT techniques. Contemporary treatment seems to be less harmful, although long-term data are not yet available.

Over the last decade, new developments in computer technology have led to an enormous evolution in RT techniques. Together with an extensive implementation of imaging modalities in the RT practice, these new techniques allow a more accurate delivery of the radiation dose.

Various modalities of radiotherapy are present which includes :-

1) Two dimensional radiotherapy (2D-RT)
2) Three dimensional confirmal radiotherapy (3D-CRT)
3) Intensity modulated radiotherapy (IMRT)

Radiation for breast cancer is predominantly to the intact breast for early stage diseasewith post-mastectomy radiation comprising a smaller proportion of radiation deliveredfor this diagnosis. The acute toxicity that develops as well as the type of late sequelae thatcan occur in each of these treatment scenarios is similar. During intact breast or chest-wallradiation, the organs commonly at risk for radiation injuries that manifest as acute and latetoxicity include skin, chest wall, lung, and heart. When regional nodal irradiation

isadded, the shoulder, brachial plexus, and axillary lymphatics are also at risk for potentialinjury.Skin reaction is the most common side effect during breast cancer radiation.

Indeed, over the course of several weeks of daily radiotherapy treatments, up to 90% of patients report fatigue (with 30% describing it as ranging from severe to intolerable), and 74%-100% of patients experience skin irritation which can range from painful redness (erythema), to open wounds (desquamation), ulceration, and necrosis. Both fatigue and skin irritation can take a substantial toll on women's quality of life (From the psychological perspective, breast cancer radiotherapy has been related to emotional distress. More specifically, research has shown that: 31% of patients experienced moderate to severe levels of negative affect; that 40% - 48.7% of patients experienced anxiety about radiotherapy, 54% - 69.1% experienced anxiety about potential radiotherapy side effects); and 40.5% experienced worry about negative radiotherapy effects on the appearance of their breast.

II. Methods and Methodology

The present study ―Observational study for effectiveness and safety profile measurement of breast cancer using 3D-CRT and IMRT‖ was conducted in department of Radiotherapy, Pt. JNM medical college and Regional cancer center (RCC) of Dr. BRAM Hospital Raipur. This thesis was approved by ethical and scientific committee Pt. JNM medical college Raipur.It was prospective study which was conducted during February 2015 – July 2016.

INCLUSION CRITERIA:-

1) Patient of carcinoma breast
2) Biopsy proven case of carcinoma breast
3) Karnofsky Performance scale (KPS)>90%

EXCLUSION CRITERIA:-

1) Patient with Karnofsky Performance scale (KPS)<90%
2) Patient with co-morbidities (heart disease , lung disease etc)
3) Patient with secondaries and metastasis

MAJOR VARIABLES:-

1) Age
2) Sex
3) Diagnosis (site left/right)
4) TNM classification
5) Stage
6) Histopathology
7) Target volume (CTV, PTV)
8) Dose [objective organ and critical structure (heart, lung)]
9) Clinical details (CBC , RFT , LFT)
10) Toxicity profile and grading.
11) Follow up.

METHODOLOGY

1) 60 patient according to above mentioned inclusion and exclusion criteria were taken under the study during the study period.
2) Written and informed consent were taken from each patient participating in the study.
3) Detail history was recorded from each patient pertaining to the onset and duration of present complaint
4) Physical examination was done on all the patient including general and systemic examination
5) All the routine investigations including haemogram X-ray chest , USG abdomen , ECG was done on all the cases
6) Half of the patient (30 patient) were taken for 3D-CRT and half of the patient (30 patient) were taken for IMRT
7) Dose to PTV and OARs was calculated in both the arms
8) Follow up was done for 6 month and local response and toxicities were noted

III. Observation And Result

In following section we are illustrating major findings of our study. We haveinterviewed 60 patients treated for CA Breast using 3D-CRT and IMRT.

Table 1: Age-wise distribution of Ca Breast patients treated under 3DCRT and IMRT technique

Technique	Age (N= 60)	
	< 50	> 50
3DCRT	28.33%	21.67%
IMRT	26.67%	23.33%

In our study maximum number of patients (55%) treated in both arms IMRT and 3D-CRT belong to age group of less than 50 years of age.

Table 2: Gender frequency of CA Breast patients

Sex	In % (N= 60)
Female	98.33%
Male	1.67%

In our study we found that male breast carcinoma cases represent less than 2% in botharms IMRT and 3D-CRT.

Table 3: Laterality and histopathology representation of CA Breast patients

HPE	Technique (N= 60)	
	3DCRT	IMRT
IDC -Left	25%	28.33%
IDC- Right	25%	21.66%

Our study data depicts that 53.33% patient treated in both arms IMRT and 3D-CRT techniques have presented with infiltrating ductal carcinoma in left breast.

Table 4: CA Breast patients representation in different quadrants

Site	**3DCRT**	**IMRT**
UOQ	31.67%	43.33%
UIQ	5.00%	6.67%
CQ	6.67%	0%
LOQ	3.33%	0%
LIQ	3.33%	0%

In our study we found that 3/4th of total patients have suffered carcinoma breast in upper outer quadrant (75%) treated in both arms IMRT and 3D-CRT techniques. All the patients treated in IMRT had disease in upper quadrants only. None of the patient treated in IMRT represented disease in either central or lower quadrant.

Table 5: Stage-wise representation of CA Beast patients

TNM Staging	**3DCRT**	**IMRT**	**TOTAL**
PT2N2M0	11.67%	16.67%	28.33%
PT3N0M0	5%	0%	5%
PT3N1M0	20%	20%	40%
PT3N2M0	11.67%	13.33%	25%
PT4N1M0	1.67%	0%	1.67%

According to our data 95% of carcinoma breast cases approached for treatment in stage III disease in both IMRT and 3D-CRT.

Table 6: Frequency of patients representing skin toxicity during treatment

Skin Toxicity	3DCRT	IMRT	Total (N=60)
Grade 0	32%	50%	82%
Grade 1	13%	0	13%
Grade 2	0	0	0
Grade 3	2%	0	2%
Grade 4	3%	0	3%

Our study reflects that skin toxicity is reported only by patients treated under 3D-CRT technique. Around 18% patients reported skin toxicity between grade I to grade IV.

Table7: Frequency of patients representing dysphagia during treatment

Dysphagia	3DCRT	IMRT	Total (N=60)
Grade 0	43%	50%	93%
Grade I	7%	0%	7%

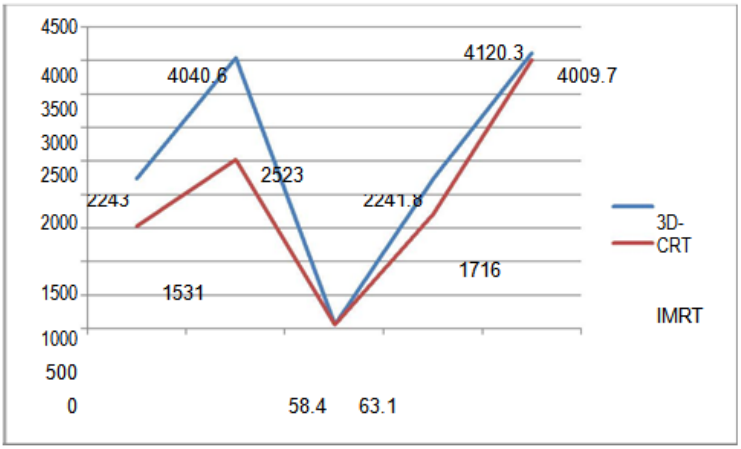
According to our study data only7 % patients treated under 3D-CRT reported grade I dysphagia mainly with complaints of difficulty in swallowing liquid and solid foods.

Table 9: Local control report during treatment

LOCAL CONTROL	3DCRT	IMRT	Total (N=60)
LOCAL FIBROSIS	5%	1.67%	6.67%
RECURRENCE	5%	0%	5%
NED	40%	48.33%	88.33%

Our study found out that local control was reported by 88.33% treated in both arm 3D-CRT and IMRT techniques. Less than 2% patients treated in IMRT reported local fibrosis and patients treate
d under 3D-CRT reported local fibrosis and recurrence 5% each.

FIGURE 1: Delivery of radiation dose and volume in 3D-CRT and IMRT



In comparison of radiation dose our data reflects delivery of lesser amount of dose in IMRT technique to heart and ipsilateral lung. In 3DCRT only contralateral lung has received lesser dose and volume. Aggregate data for radiation reports delivery of lesser and better amount of dose and volume to organs at risk under IMRT technique.

IV. Discussion

This observational study carried out in 60 cases at Pt. JNM medical college and associated Regional cancer center of Dr. BRAM Hospital Raipur CG in department of radiotherapy for assessing effectiveness and safety profile for treatment of breast cancer using 3D-CRT and IMRT. It included all the patient with biopsy proven carcinoma breast with detail clinical history which included surgery and chemotherapy followed by complete hemogram , ECG and radiological examination . Of these 60 patient 30 patient were treated with 3D-CRT and 30 patients with IMRT. Post treatment follow up was done from 1-6 month. Dose to PTV and OARs were calculated (mean value) in both the arms. Local response toxicities and recurrence were compared in both the arms.

AGE – (Table 1) In our study maximum number of patients (55%) treated in botharms IMRT and 3D-CRT belong to age group of less than 50 years of age**.**

SEX-*(Table 2)*In our study we found that male breast carcinoma cases represent lessthan 2% in both arms IMRT and 3D-CRT.

HISTOPATHOLOGY AND LATERALITY (Table 3) Our study data depicts that53.33% patient treated in both arms IMRT and 3D-CRT techniques have presented with infiltrating ductal carcinoma in left breast.

SITE (QUADRANT)(Table 4) In our study we found that 3/4thof total patients havesuffered carcinoma breast in upper outer quadrant (75%) treated in both arms IMRT and 3D-CRT techniques. All the patients treated in IMRT had disease in upper quadrants only. None of the patient treated in IMRT represented disease in either central or lower quadrant.

STAGING(Table 5)
According to our data around 95% of carcinoma breast cases approached for treatment in stage III disease in both arms IMRT and 3D-CRT technique.

SKIN TOXICITY (Table 6) Our study reflects that skin toxicity is reported only bypatients treated under 3D-CRT technique. Around 18% patients reported skin toxicity between grade I to grade IV.

DYSPHAGIA (Table 7) According to our study data only7 % patients treated under3D-CRT reported grade I dysphagia mainly with complaints of difficulty in swallowing liquid and solid foods.

LOCAL CONTROL AND RECURRENCE- (TABLE 09) Our study found out thatlocal control was reported by 88.33% treated in both arm 3D-CRT and IMRT techniques. Less than 2% patients treated in IMRT reported local fibrosis and patients treated under 3D-CRT reported local fibrosis and recurrence 5% each.

DOSE, VOLUME, HISTOGRAM (Figure 1) In comparison of radiation dose our data reflects lesser amount of dose in IMRT technique to heart and ipsilateral lung. In 3DCRT only contralateral lung has received. lesser dose and volume. Aggregate data for radiation reports delivery of lesser and better amount of dose and volume to organs at risk under IMRT technique.

V. Conclusion

In this study 60 patients of carcinoma breast were included, out of which 59 (98.33%) were females and 1(1.67%) was male, in female group 33(55%) were less than 50 years of age, 32(54%) patients had left sided disease and 28(46%) patients had right sided disease.

30 (50%) patients were treated with IMRT and 30 (50%) patients were treated with 3D-CRT by hypofractionated regime which included 267cGy per fraction in 15 fractions with total dose of 4005cGy and follow up was done for 6 month. Dose to PTV and OARs was calculated in both the arms & toxicities (skin toxicities and dysphagia), local control was noted.

11 (18%) patients developed skin toxicities in 3D-CRT while no skin toxicities were noted in IMRT. Similarly 5(7%) patients developed grade 1 dysphagia treated with 3D-CRT while no patient developed dysphagia after being treated with IMRT.

Dose volume histogram were calculated for different OARs and PTV in both arms which included 30% volume of heart , 20% volume of I/L lung, 20% volume of C/L lung, 20% volume of total lung and 95% volume of PTV and conformity index. No difference in conformity index was seen but IMRT improves the homogeneity index. The mean dose to all OARs was lesser in IMRT as compared to 3D-CRT of which dose to heart and I/L lung was significantly lower with IMRT (1531 cGy vs 2243cGy and 2523 cGy vs 4040.6 cGy).

Tangential beam IMRT in breast cancer offers the potential to significantly reduce the dose to I/L lung and dose to the heart which will translate into decrease in risk of cardiac and lung toxicities. IMRT also decreases the acute skin reactions in all the patients

The null hypothesis for this test was that the means for the two variables(doses of 3D-CRT and IMRT) are equal. Based on the test statistic, t stat for the above hypothesis testing, we can see that the observed t Stat (15.85) is higher than the critical t stat for the two-tail test (2.03) at a 5% confidence interval. Further the p value for the two-tail test confirms that the above test is significant at a 5% confidence level. Hence, we can reject the null hypothesis and conclude that the mean of the two variables are different.

Performing a 1-tail test, we tested for the alternative hypothesis that the mean of variable 1(dose of 3DCRT) is greater than the mean of variable 2(dose of IMRT). The observed test statistic t stat for the test (15.85) is higher than the critical 1 sided t test (1.69). Hence, we can reject the null hypothesis at a 5% confidence interval and conclude that the mean of variable 1(dose of 3D-CRT) is greater than the mean of variable 2(dose of IMRT).

applying unpaired t test to our data the p value came out to be <0.001 which is highly significant as compared to standard p value of <0.05 hence the study is statistically proven that IMRT is better than 3D-CRT in treating carcinoma breast.

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