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Hypofractionated Radiotherapy for Breast Cancer: An Indian Experience

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Abstract:
Background: *Radiotherapy is an integral part of management in all breast conservation surgeries (BCS) and for a large percentage of postmastectomy patients. Conventionally fractionated radiotherapy (1.8-2 Gy/fraction) lasts for 6 weeks in post-BCS patients and 5 weeks for postmastectomy patients. However, over last 02 decades few large randomized control trials have confirmed that appropriately dosed hypofractionated radiotherapy is equally safe and effective. Here we present our institutional experience with hypofractionated radiotherapy in breast carcinoma.*
Objectives: *Locoregional control, acute normal tissue toxicities, cosmesis*
Materials and methods: *In this prospective, single arm, single institutional, phase II study, between July 2013 to December 2015, 94 early and locally advanced breast carcinoma patients have received hypofractionated radiotherapy (40 Gy/15#/03 weeks followed by 12.5 Gy/05#/01 week as applicable). After completion of radiotherapy patients were followed up every 03 monthly and assessed for locoregional control, toxicities and cosmesis clinically.*
Results: *94 women (46 post BCS and 48 post MRM) received hypofractionated radiotherapy between July 2013 and December 2015. After a median follow up of 31 months 1 patient each developed local and regional recurrence and 2 patients developed distant metastasis. No post-BCS patient developed in-breast recurrence. Median DFS was 31 months (95% CI 28.94-33.06). There was no grade 4 acute toxicity and at the time of last follow up 16 patients (17 %) had fair, 28 patients (29.8%) had good and 2 patients (2.1%) had poor cosmesis.*
Conclusion: Hypofractionated radiotherapy is safe and effective across both early and locally advanced breast carcinoma with good cosmetic outcome.
Key Words: *Hypofractionation, Breast cancer, cosmesis*

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Introduction

Breast cancer is the leading cause of cancer death among women around the world [1,2]. Radiation therapy is an integral part of management in all breast conservation surgeries (BCS) and for a large percentage of post-mastectomy patients. Radiation therapy not only improves local control, but it also improves survival, presumably by preventing seeding of distant metastases from persistent reservoirs of loco-regional disease [3].

Conventionally, a dose per fraction per day of 1.8 to 2 Gy has been used in treatment of breast cancer. [3, 4] Hypofractionation of radiation treatment involves the use of larger daily doses of radiation and decreases the total number of fractions that has to be delivered. As the α/β ratio of breast adenocarcinoma of around 3 Gy (close to late reacting normal tissue) [5] more tumour cells will be killed by hypofractionation. [6]

With mature follow-up of 10 years in all trials, which together treated more than 6,500 patients, these studies demonstrate that hypofractionation yields equivalent or improved outcomes in efficacy (both local and distant disease control), toxicity, cosmesis, and cost-effectiveness compared to conventional fractionation.

So, in a developing country like India, a shorter breast radiotherapy schedule would be more convenient for patients (especially those coming from remote areas to radiation facilities).

Unfortunately, the published data from the Indian experience is still quite limited; our study is therefore a valuable record of experience of an Indian cancer center with hypofractionated radiotherapy for breast cancer.

Materials and methods

Between July 2013 and December 2015, 94 consecutive patients of non-metastatic breast cancer received post-operative radiotherapy at our center. Radiotherapy was started 2-3 weeks after completion of chemotherapy or as soon as surgical wound healed. Hormone receptor-positive patients were encouraged to start their endocrine therapy while on radiotherapy. HER-2 positive patients continued receiving adjuvant Trastuzumab while on radiotherapy.

All patients underwent a planning plain CT scan with 5mm slices on our CT simulator (Somatom Emotion 16-slice CT scanner) followed by delineation of target and organs at risk on Focal Sim software (version 4.80.02). Targets (whole breast/chest wall) were drawn as per the RTOG guidelines [10], while the GEC-ESTRO guidelines [11] on partial breast irradiation were used to delineate the boost cavity. Treatment planning was done on the CMS XiO software (version 4.80.00.7). The supraclavicular lymph node region was irradiated in all patients with metastasis to axillary lymph nodes. Radiation to the axilla was given only in cases of inadequate axillary dissection or presence of gross residual disease in the axilla. Radiation to the internal mammary region was suggested only if found to be present pathologically.

For whole breast or chest wall, two tangential 6MV beams with MLC shaping were set and subfields were added to improve dose coverage or homogeneity. For the supraclavicular fossa, a single anteroposterior beam was used. For tumor cavity, conformal boost with 6MV photons was planned with 3-5 coplanar beams. All patients underwent treatment on the Compact 6MV linear accelerator (Elekta AB, Sweden). Prescribed dose was 40 Gy in 15 fractions over 3 weeks to whole breast or chest wall and supraclavicular fossa followed by 3D conformal boost to tumor cavity (for post-BCS patients) to a dose of 12.5 Gy in 5 fractions. Planning constraints were to minimize the dose to the cardiac apex (for left sided tumors) (V25 <10% and V30 < 46% and mean pericardial dose <26 Gy) [12] and to keep the V20 for both lungs to below 30% [13].

Acute (dermatitis, pain, dysphagia) and late toxicity data of radiotherapy were recorded as per RTOG acute and late morbidity scoring criteria [14] and the cosmesis was evaluated clinically using Harvard criteria [15] at the end of radiotherapy and during each follow up thereafter (03 monthly). In each follow up we evaluated the patient clinically and radiologically (if required) to look for any locoregional or distant metastasis.

Results

A total of 94 patients of all stages (except stage IV) were treated in our set up between July 2013 and December 2015 of whom 46 were post-BCS (48.9%) and 48 were post-mastectomy (51.1%). Mean age of the whole population (both mastectomy and BCS patients) was 53.32 years. The number of patients with right and left sided breast cancer were equally distributed. 25.5% patients (n=24) were premenopausal and 7.4% (n=7) and 67% (n=63) patients were peri and postmenopausal respectively.

Most of the patients were ER positive (62.8%), PR positive (55.3%) and Her 2 neu negative (67.0%). As per Luminal classification most of the patients were of Luminal A subtype (56.4%); subsequently followed by triple negative subtype (25.5%), luminal B subtype (9.6%) and Her 2 over expressive subtype (8.5%). (Table 1)

Most of the patients had grade II tumour (56.4%) followed by grade III (31.9%) and grade I tumour (11.7%). Regarding tumour size, 9 patients were of cT1 stage (9.6%), 57 patients were of cT2 stage (60.6%), 16 patients were of cT3 stage (17%), 11 patients were of cT4 stage (11.7%) and 1 patient were of unknown tumour size.

Clinically 39 patients were node negative (41.5%) and 55 patients were node positive (58.5%); out of which 36 patients with cN1 disease (38.3%), 16 patients with cN2 disease (17%) and 3 patients with cN3 disease (3.2%). In overall stage grouping 9 patients were in stage I (9.6%), 35 patients were in stage IIA (37.2%), 18 patients were in stage IIB (19.1%), 20 patients were in stage IIIA (21.3%), 8 patients were in stage IIIB (8.5%), 2 patients were in stage IIIC (2.1%); while 1 patient's stage was unknown as the patient came with inadvertent surgery beforehand and inadequacy of histopathology report.

Based upon HPR report most common T stage was of pT2 stage (58.5%) followed by pT1 stage (20.2%), pT3 stage (10.6%), pT0 (6.4%) (complete resolution of tumour after NACT) and lastly pT4 stage (4.3%). Among other histopathological parameters 5.3% patients were with multifocal and 1.1% patients were with multicentric tumour, in 50% cases there were DCIS and in 4.3% cases there were EIC, 53.2% cases with LVSI (+) and 20.2% with PNI (+), most of the cases were margin negative; only 3.2 % cases were close margin, 2.1% cases were margin positive and in one case margin status was unknown due to inadequate HPR report. Regarding postop nodal positivity most of the patients were of pathologically node negative (pN0; 38.3%), 33% patients were of pN1 stage, 16% were of pN2 stage, 10.6% patients were of pN3 stage and 2 patients underwent MRM with axillary clearance but due to inadequacy of HPR report pathological N staging could not be done. Out of the node positive cases in 29.8% cases there were perinodal extension.

23.4% patients received NACT and 64.9% patients received adjuvant chemotherapy, mostly with Anthracycline and Taxane based regimen. Any form of chemotherapy (neoadjuvant or adjuvant) was avoided in 17% patients (n=16) as they were of early stage tumour (pT1/2N0 with hormone receptor positive). Another 7 patients (7.44%) declined chemotherapy; out of them 3 were above 70 years of age and not fit for chemotherapy.

Skin toxicity grading was done according to RTOG criteria [14]. There was no grade 4 acute or late toxicity. Only 3.2% patients (n=3) experienced grade 3 acute skin toxicity and in the rest of the patients 4.3% (n=4) patients had grade 2 and 92.6% (n=87) patients developed grade 1 acute skin toxicity. 68 patients had received radiation to supraclavicular fossa and out of those patients 12.8% (n=12) patients suffered from grade 2 and 59.6 % (n=56) patients suffered from grade 1 dysphagia. After completion of radiation patients were on 3 monthly follow up. On follow up 4.3% developed grade 2 late skin toxicity and only 1 patient (1.1%) developed grade 3 subcutaneous fibrosis. At the time of analysis 4 patients (4.25%) had persistent skin hyperpigmentation and 5 patients (5.31%) had lymphedema.

On median follow-up of 31 months, 1 patient each developed local and regional recurrence and 2 patients developed distant recurrence. Among the patients who failed distally one patient was of stage IIIC patient (cT4N3M0), triple negative, post MRM and developed brain metastasis (DFI 18 months) and the other one developed lung metastasis and were of stage IIIC, Luminal A, post MRM (DFI 22 months). One patient (stage IIIA, Luminal A, post NACT, post MRM) developed local recurrence (recurrence at axillary tail; detected by mammogram and confirmed by excision biopsy) and one patient (stage IIB, Her 2 over expressive, post NACT, post MRM) developed supraclavicular lymph nodal recurrence. No post-BCS patient developed in-breast recurrence.

At the time of last follow up 87 patients (92.6%) remained alive and disease-free, while there were 4 deaths, of which 1 was due to cancer (1.1%) and 3 patients were alive with disease (3.2%). Mean disease-free survival (DFS) was 30.2 months (96% CI 28.66-31.74), median DFS was 31 months (95% CI 28.94-33.06). (Figure 1)

Complete cosmetic outcome data were available for 46 patients (48.9%). At the time of radiation conclusion 20 patients (43.5%) had fair, 24 patients (52.2%) had good and 2 patients (4.4%) had excellent cosmesis. But with follow up there were gradual changes of cosmesis and at the time of last follow up 28 patients (60.9%) had good, 16 patients (34.8%) had fair and 2 patients (4.4%) had poor cosmesis.

Discussion

Whole breast radiotherapy is the standard of care following BCS as it positively impacts both locoregional control and overall survival, while most high-risk post-mastectomy patients will also need to receive radiotherapy to the chest wall and/or supraclavicular fossa for locoregional control. Clarke et al. [16] for the EBCTCG showed in women with early breast cancer, radiation after BCS reduces the risk of local relapse by about 70% and reduces absolute breast cancer mortality by 5.4%.

The standard of care for whole breast/chest wall radiotherapy used to be 45-50 Gy in 25 fractions over 5 weeks, a protocol which evolved somewhat empirically. Assuming lower α/β ratio of the breast tissue [17] leading to its higher sensitivity to fraction size; over the last two decades there were multiple randomized control trial comparing conventionally fractionated radiotherapy versus hypofractionated radiotherapy. Royal Marsden Hospital/Gloucestershire Oncology Centre (RMH/GOC) trial [18] have compared three different radiotherapy schedules (50 Gy in 25 fractions, 39 Gy in 13 fractions, or 42.9 Gy in 13 fractions, all given over 5 weeks) in 1410 early breast cancer patients between 1986-1998 and have showed reduction in local recurrence in 3.3 Gy per fraction arm at 10 yrs of follow up.

So, initial success with hypofractionated radiotherapy led to the design of the START-A and START-B trials in the UK. START A trial [19] showed similar locoregional relapse rate with hypofractionated arm in 2,236 women with early breast cancer (pT1-3a, pN0-1, M0). Similar kind of results were obtained from Ontario [20] and START B trial. In UK START B trial [21] between 1999 and 2001; 2,215 women with early breast cancer were randomly assigned after primary surgery to receive 50 Gy in 25 fractions over 5 weeks or 40 Gy in 15 fractions over 3 weeks. Locoregional tumor relapse rate at 5 years were 2.2% in 40 Gy group and 3.3% in 50 Gy group. So, both the START A and START B trial conclusively established that hypofractionated radiotherapy is as good as conventionally fractionated radiotherapy. In our study, we have used the START-B protocol of 40 Gy in 15 fractions over 3 weeks for our patients.

Although the START trials did not routinely use any further dose to the tumor bed, Bartelink et al [22] showed there was significantly improved locoregional control (local recurrence rate was 10.2% versus 6.2% in no boost and the boost group, respectively; $P < 0.0001$) at 10 yrs follow up albeit increase in the severe fibrosis in the boost group and no difference in overall survival, On the other hand, the dose and fractionation used for boost has remained heterogeneous: dose has varied from 12-20Gy, delivered by both conventional fractionation and hypofractionation. In our institute, we have been using 12.5 Gy in 5 fractions 3D conformal photon boost.

The late effects on normal tissues and breast cosmesis are important issues in hypofractionated schedules. Most common changes of breast after radiation is shrinkage (atrophy); but edema, fat necrosis, retraction, and telangiectasia also responsible for changes in breast appearances after radiation. Cosmesis has been shown to depend largely on post-radiation fibrosis. Recent studies have shown that intensity modulated radiotherapy can facilitate a homogenous dose distribution and also a more conformal cavity boost. There are also various subjective and objective indices of cosmesis. In RMH/GOC trial [18] they have used annual photograph to score for changes in breast appearances and clinically palpable breast induration as marker for fibrosis. In this study 3.3 Gy per # schedule showed the worst cosmetic results. In contrast START A trial [19], by photographic and patient self-assessments, suggested lower rates of late changes in breast appearance after 39 Gy than with 50 Gy, with a hazard ratio (HR) of 0.69 (95% CI 0.52–0.91, $P = 0.01$). whereas, the UK START B trial [21] have shown a lower rate of change in breast appearance after 40 Gy in 15 fractions regimen (hazard ratio (HR) = 0.83; 95% CI, 0.66–1.04; $P = 0.06$). UK FAST trial [23] also showed comparable cosmesis between conventional and hypofractionated arm. But neither photographic appearance nor induration can record damage to underlying pectoral muscle or rib cage.

There have also been some concerns raised by many clinicians about hypofractionated radiotherapy to the supraclavicular fossa, with the risk of brachial plexopathy. Yarnold et al [5] have shown in the toxicity analysis of pooled patients from the START trials, the EQD2 to the brachial plexus is lower than with a conventionally fractionated protocol (EQD2 is 47 Gy if the α/β value for brachial plexus is 2.0 Gy or EQD2 is 49 Gy if α/β is 1.0 Gy) and thus hypofractionation is actually more nerve-sparing. Galecki et al. [24] showed the risk of radiation- induced brachial plexopathy was <1% after administration of doses per fraction between 2.2 and 2.5 Gy with the total dose between 34 and 40 Gy. When biologically effective dose was above 55 Gy, the risk of radiation- induced brachial plexopathy increased rapidly. In our study, there were no cases of brachial plexopathy recorded.

Though there is paucity of literature on hypofractionated postmastectomy radiotherapy to chest wall; but recently Guang -yi Sun et al [25] from China presented results of the randomized control trial between conventionally fractionated RT and hypofractionated radiation and showed there is no significant difference in 5 year clinical outcomes or toxicity (except acute Gr III skin toxicity which was less in hypofractionated arm) at a median follow up of 53 months.

Similarly, Atif J Khan et al published the first results of the phase II trial on Hypofractionated Postmastectomy Radiation [26] and demonstrated low toxicity and high local control with hypofractionated schedule. They have delivered PMRT to the stage II and IIIA breast cancer patients at a dose of 36.63 Gy in 11 fractions (3.33 Gy/fraction) over 11 days to the chest wall and the draining regional lymph nodes, followed by an optional mastectomy scar boost of four fractions of 3.33 Gy. After median follow up of 32 months there was no grade 3 toxicities and three-year estimated local recurrence-free survival and distant recurrence-free survival were 89.2% (95% CI, 0.748 to 0.956) and 90.3% (95% CI, 0.797 to 0.956) respectively.

There is still inadequate data on late lung and cardiac morbidity and survival rate for the current hypofractionation schedules. Early Breast Cancer Trialists' Collaborative Group [27] have reported that radiation therapy reduces the annual mortality from breast cancer by 13%, but increases the annual mortality rate from other causes by 21%, mostly due to cardiovascular causes, even with conventional fractionation schedule. Hypofractionation may cause the situation worse but we have to wait until at least 15 years after treatment to have a clear idea about the late cardiovascular toxicities.

Finally, there are few logistics issues also which favors hypofractionated RT in a resource constraint country like ours. Hypofractionated RT decreases overall treatment time that leads to decrease treatment expenses from

the patient point of view, increases patient turnover rate of the department, decreases long waiting time and machine maintenance cost also.

Conclusion

Hypofractionated breast radiotherapy is safe and effective across both early and advanced stages with good cosmetic outcome. The paucity of published Indian data served as an initial deterrent for its widespread use but the present experience suggests that hypofractionated radiotherapy for breast cancer may replace conventionally fractionated radiotherapy as the standard of care in India.

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Figure 1: Kaplan Meyer Plot showing Disease free survival

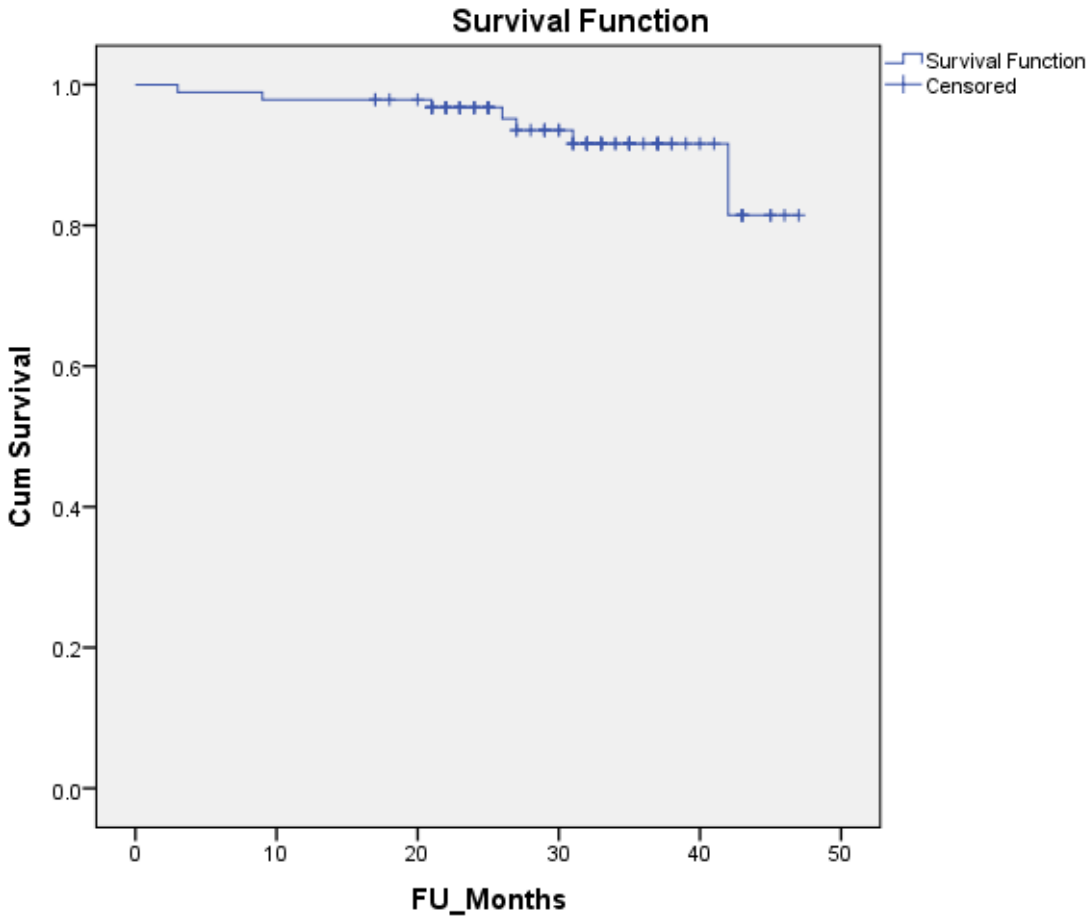

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Table 1: Demographics and Clinical characteristics of the patients

	Number of patients	Percentage of patients (%)
Menopausal status		
Premenopausal	24	25.5
Perimenopausal	7	7.4
Postmenopausal	63	67
Tumour Grade		
Grade I	11	11.7
Grade II	53	56.4
Grade III	30	31.9
Surgery		
BCS	46	48.9
MRM	48	51.1
Axillary Clearance	88	93.6
SLNB	6	6.4
Luminal Status		
Luminal A	53	56.4
Luminal B	9	9.6
Her 2 Over-expressive	8	8.5
TNBC	24	25.5
Ductal Carcinoma in situ		
Absent	34	36.2
Present	47	50
Unknown	13	13.8
Margin Status		

Negative	88	93.6
Close	3	3.2
Positive	2	2.1
Unknown	1	1.1
Pathological T staging		
0	6	6.4
1	19	20.2
2	57	60.6
3	10	10.6
4	2	2.1
Pathological N staging		
0	36	38.3
1	31	33.0
2	15	16.0
3	10	10.6
Unknown	2	2.1