Original Article

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Website: https://journals.lww.com/aort

DOI: 10.4103/aort.aort_48_24

A prospective feasibility study on extreme hypofractionation in adjuvant radiation of breast cancer in a tertiary cancer center in India

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Submitted: 02-Dec-2024
Revised: 26-Dec-2024
Accepted: 27-Dec-2024
Published: 12-May-2025

Abstract:

INTRODUCTION: Breast cancer is the most common cancer among women in India at present, having overtaken cancer cervix. Treatment of breast cancer is a multimodality approach. Adjuvant radiation therapy plays a major role in the treatment of breast cancer. Standard of care in adjuvant therapy changed from conventional fractionation to hypofractionation with the advent of START A and START B trials. In 2020, the Fast Forward Trial group released their 5-year results showing noninferiority results in patients treated with 27/26 Gy in 5 fractions compared to 40 Gy in 15 fractions. Studies supporting the extreme hypofractionated regimen are not available in the Indian scenario. The purpose of this study is to evaluate the feasibility of extreme hypofractionated radiation in breast cancer in Indian setup and to assess the acute toxicities of patients during and postradiation.

AIMS AND OBJECTIVES: To study the feasibility and acute toxicities of 1-week extreme hypofractionated regimen adjuvant radiation therapy for breast cancers in Indian scenario.

MATERIALS AND METHODS: A total of 25 patients who are pathologically proven breast cancer, invasive ductal carcinoma (IDC) grade 1–3, postsurgery breast-conserving surgery and mastectomy, pT1-T3 or N0-N1, irrespective of hormonal receptor and Her 2 neu and chemotherapy are enrolled into the study during a period of September 2021–May 2022. Patients received 27 Gy in 5 fractions at 5.4 Gy per fraction to the whole breast/chest wall with a sequential boost of 11 Gy in 3 fractions at 3.67 Gy per fraction as boost to the tumor bed in patients who underwent breast conservation surgery. Patients have been evaluated for acute toxicities as per the common terminology criteria for adverse events 3.0 during radiation and up to 1-month postradiation therapy. Patient-reported breast cancer-specific quality of life has been evaluated using the validated European Organization for Research and Treatment of Cancer Breast Cancer-Specific Quality of Life Questionnaire at the time of simulation (baseline), treatment completion, and first, follow-up.

RESULTS: Acute skin toxicities are not noticed during radiation in the majority of patients. They developed skin reactions during 2–4 weeks postradiation, which subsided within 4 weeks. Twenty (80%) patients had Grade 1 reactions, 2 (8%) patients had Grade 0, and 3 (12%) patients had Grade 2 acute skin toxicities like patchy moist desquamation, which started in the 2nd week and resolved in 4 weeks after radiation. In terms of patient quality of life, acute breast-related symptoms were analyzed, and 5 (20%) patients complained of moderate breast symptoms such as pain, swelling, and skin problems immediately after the completion of radiation therapy, which subsided at 1-month postradiation.

How to cite this article: Muddana SS, Palkonda VA, Kavikondala M, Upadhyaya P, Reddy VK, Keesara SR, *et al*. A prospective feasibility study on extreme hypofractionation in adjuvant radiation of breast cancer in a tertiary cancer center in India. Ann Oncol Res Ther 0;0:0.

CONCLUSION: One-week hypofractionation in breast cancer radiation therapy is feasible in the Indian subset of population. Majority of patients developed Grade 1 and 2 acute skin toxicity, which resolved without any intervention. There were no grade 3 and 4 acute toxicities during radiation. Few patients reported moderate breast symptoms immediately after completion of radiation therapy, which subsided within 1 month.

Keywords:

Breast, hypofractionation, radiation therapy

Introduction

Breast cancer is the most common cancer among women in India at present, having overtaken Cancer Cervix.[1] The annual incidence of breast cancer in India is 2261,419 in 2020. The Early Breast Cancer Trialists' Collaborative Group systematic overview[2] established the role of adjuvant radiation therapy in patients both in postbreast-conserving surgery (BCS) and post mastectomy settings.

The fractionation schedule of radiation has evolved over time. Conventional fractionation schedule of 50 Gy dose in 25 fractions[3,4] with 2 Gy per fraction was standard of care for decades. START A[5] and START B[6] trials were instrumental in establishing the role of hypo-fractionated radiation therapy in breast cancer. Recent data suggest that the alpha/beta value of breast tumors is low, ranging from 2 to 4,[7] which confers a radiobiological advantage with hypofractionated regimens. The logistic benefits of hypofractionation have also been instrumental in its fast acceptance.

Hypofractionation is defined as increasing the dose per fraction to more than 2.2 Gy per day to reduce overall treatment time. Two basic schools of larger-than-conventional fraction sizes have been commonly explored: moderate hypofractionation, encompassing doses of 2.2-4 Gy per fraction,[8] and extreme hypofractionation (otherwise known as "SBRT," "aggressive hypofractionation," or "stereotactic ablative body radiotherapy,") typically encompassing doses of 4–15 Gy per fraction.[9]

As per the IAEA-DIRAC database,[10] each radiotherapy center serves 2–5 million population in India. As the disease burden is expected to increase, shorter treatment times and reduced operating costs are going to play an important role in keeping check to spiraling budget of health care.

Patients often travel to far away places for their treatment and stay away from home for longer times. This problem is more often in patients who are receiving radiation therapy, as radiation is a daily treatment. Reducing the treatment time with equal clinical benefit will help such patients. This will also help in increasing the number of patients treated in a given period of time without increasing the burden on healthcare workers.

As moderate hypofractionation is more or less the standard of care across many institutes in the country and is proven to be safe, the role of extreme hypofractionation is being investigated. It has more importance in elderly patients with multiple comorbidities, accounting both for ease of treatment, and social factors.

In 2020, the Fast Forward Trial[11] group released their 5-year results showing noninferiority of, local tumor control in patients treated with 1-week extreme hypofractionated regimen compared to established three weekly regimens. The COVID-19 pandemic and related restrictions also played a role in the fast adaptation of shorter treatment protocols. This study was published in 2020 and there is a lack of data in Indian set up so far. We wanted to explore if we would be able to do this extreme hypofractionation-based radiation planning in our facilities with respect to patient load, time factors, and infrastructure and also will be able to achieve the specified dosimetric constraints with our population biological parameters (body-built, chest wall contour, and lung volumes) which vary from the European population.

The purpose of this study is to evaluate the feasibility of extreme hypofractionated radiation in breast cancer in Indian setup and to assess the Acute toxicities of patients during and post radiation.

Materials and Methods

A total of 25 patients who were advised adjuvant radiation therapy for early breast cancer at Apollo Hospitals, Hyderabad, were recruited into the study based on the inclusion criteria from September 2021 to May 2022.

Patients who were older than 18 years of age, willing to consent to participate in the study, with histologically proven breast cancer, staged: PT1-T3, pNo-N1, cM0, who underwent either breast conservation surgery or mastectomy, who received neoadjuvant or adjuvant chemotherapy were included in the study. Concurrent-targeted therapy with anti-Her2 neu therapy or hormonal therapy was allowed. Patients with prior Radiation therapy to the chest wall, patients with locally advanced breast cancer, patients who underwent oncoplastic reconstruction postprimary surgery, patients with associated comorbid conditions

that contraindicate chest wall irradiation like ischemic heart disease, congestive heart failure, Left ventricular failure, connective tissue disorders, etc., were excluded.

Informed consent was obtained from those willing to participate. Patient demographic information and basic laboratory data were recorded. Physical examination was done, and the patient was taken up for radiation planning.

Radiation Simulation was done with the patient lying down in a supine position and arms kept above the head. Immobilization using the thermoplastic mask was done. As per the patient's anatomy, if required, a breast board with the angle of 5°–15° was used. Three fiducial markers were placed on the thermoplastic mask for reference. Radiation planning computed tomography (CT) scan was taken with contrast-enhanced CT scans obtained at 2 mm serial intervals, including neck to mid abdomen. In BCS patients scar, nipple-areolar complex, superior, inferior, medial, and lateral borders of the breast were marked with radio-opaque wire. In Magnetic resonance mammography patients surgical scar and opposite side breast borders were marked with radio-opaque wire. Another plain CT scan was obtained with the wire marker in 2 mm intervals. Both these scans were imported into the planning system and fused with the help of image registration. In breast conservation surgery patients, this scan was compared with presurgery scans to delineate the target volumes of the tumor bed.

Target volume delineation was done according to European Organization for Research and Treatment of Cancer (EORTC) guidelines.[12] Organs at risk were contoured as per RTOG guidelines.[13]

The whole breast Clinical target volume (CTV) (CTVWB) [Table 1] includes the soft tissues of the whole breast from 5 mm below the skin surface down to the deep fascia, excluding coastal, intercoastal muscles and the underlying rib cage. The posterior margin should not extend beyond the deep fascia (unless clearly breached by the tumor). If the anatomy of this region cannot be easily visualized, the posterior margin should be limited to 5 mm anterior to the lung/chest wall interface. CTVWB should not extend beyond the edges of the visible/palpable breast in medial and lateral directions. A 7 mm margin was added to create the whole breast Planning target volume (PTV) (PTVWB). The treatment fields should be positioned to cover the unmodified PTVWB with an appropriate margin for the penumbra.

Table 1: Target volume definitions

	CTV	PTV
WB	CTV WB=soft tissues of whole breast	PTV WB=CTVWB +7 mm margin
CW	CTV CW=skin flaps and soft tissues	PTV CW=CTVCW +7 mm margin
Boost	CTV TB=tumor bed	PTV TB=CTVTB +7 mm margin

CW=Chest wall, WB=Whole breast, CTV=Clinical target volume, PTV=Planning target volume

CTV tumor bed (CTV TB) [Table 1] was outlined by drawing around the implanted markers and any changes in the surrounding tissue architecture. This was correlated with pretreatment diagnostic imaging, if available, to confirm the location. For patients with no visible seroma and the presence of surgical clips, contouring was done around the clips and adding a 10 mm margin to it to obtain the CTV. For patients without clips or seroma, CTV TB was outlined by following the pretreatment tumor location and postoperative changes visible radiologically, provided a proper fusion of preoperative and postoperative scans was possible. This was grown by 7 mm to give the tumor bed PTV or PTVTB. When planning the tumor bed boost, the treatment fields were positioned to cover the unmodified PTVTB with an appropriate margin for the penumbra.

The chest wall CTV [Table 1] encompasses the skin flaps and includes the soft-tissues down to the deep fascia, excluding the underlying muscle and rib cage. A 7 mm margin was added to create the chest wall PTV.

The ipsilateral lung was outlined as a single structure, and care was taken not to include any air ways or major blood vessels.

The whole heart was outlined to the extent of the pericardial sac (if visible). The major blood vessels (superior to the organ) and the inferior vena cava (towards the inferior extent of the heart) were excluded. The point where the pulmonary trunk and the right pulmonary artery are seen as separate structures was used as an indication of the superior extent of the heart.

Dose prescription

PTV whole breast or Chest wall: 27 Gy in 5 fractions at 5.4 Gy per fraction, followed by a tumor cavity boost of 11 Gy in 3 fractions at 3.67 Gy per fraction in post-BCS patients.

The treatment planning system used was Eclipse, and planning was done using either conventional tangential planning, inverse planned intensity-modulated radiation therapy (IMRT), field-in-field IMRT or volumetric-modulated arc therapy (VMAT). For every patient, a 3DCRT plan, IMRT plan, and VMAT plan were generated, and then, the plan with the best coverage and organ-at-risk (OAR) sparing was used. In the VMAT plan, hemi arcs were used to avoid low-dose spillage. The planning targets [Table 2] were followed strictly as per the Fast Forward protocol.[14]

The volume of the ipsilateral lung receiving 8.0 Gy should be <15% optimally, mandatory dose was V8 <17%. The volume of the heart receiving 1.5 Gy and 7.0 Gy should be <30% and 5%, respectively [Table 3].

Treatment delivery was done on the Novalis Tx Linear Accelerator/True beam machine. Daily patient setup was verified by the radiation oncologist. Daily image verification of treatment area done with either KV CBCT or MVCBCT imaging by the radiation oncologist [Figure 1].

Table 2: Planning targets

	Mandatory	Optimal
Lower limit	V95% ≥ 90%	V95% ≥ 95%
Upper limit	V105% ≤ 7%	
	V107% ≤ 2%	
	Dmax ≤ 110%	

Acute toxicities were assessed using Common Terminology Criteria for adverse events version 3.0 during radiation, immediately after 1 month and at 3 months follow-up. At each follow-up visit, patient's medical history and physical examination were assessed.

Results

Patient characteristics

Median age was 52 years (34–62 years). Majority of patients were staged pT2N0. Eighty percent of patients were IDC grade 3. Sixty-four percent of patients were post BCS patients who received whole breast Radiation therapy along with boost. Sixty percent of patients have been treated for right-sided breast cancer. Eighty-four percent of patients received adjuvant chemotherapy. Fifty-two percent of patients received adjuvant hormonal therapy [Table 4].

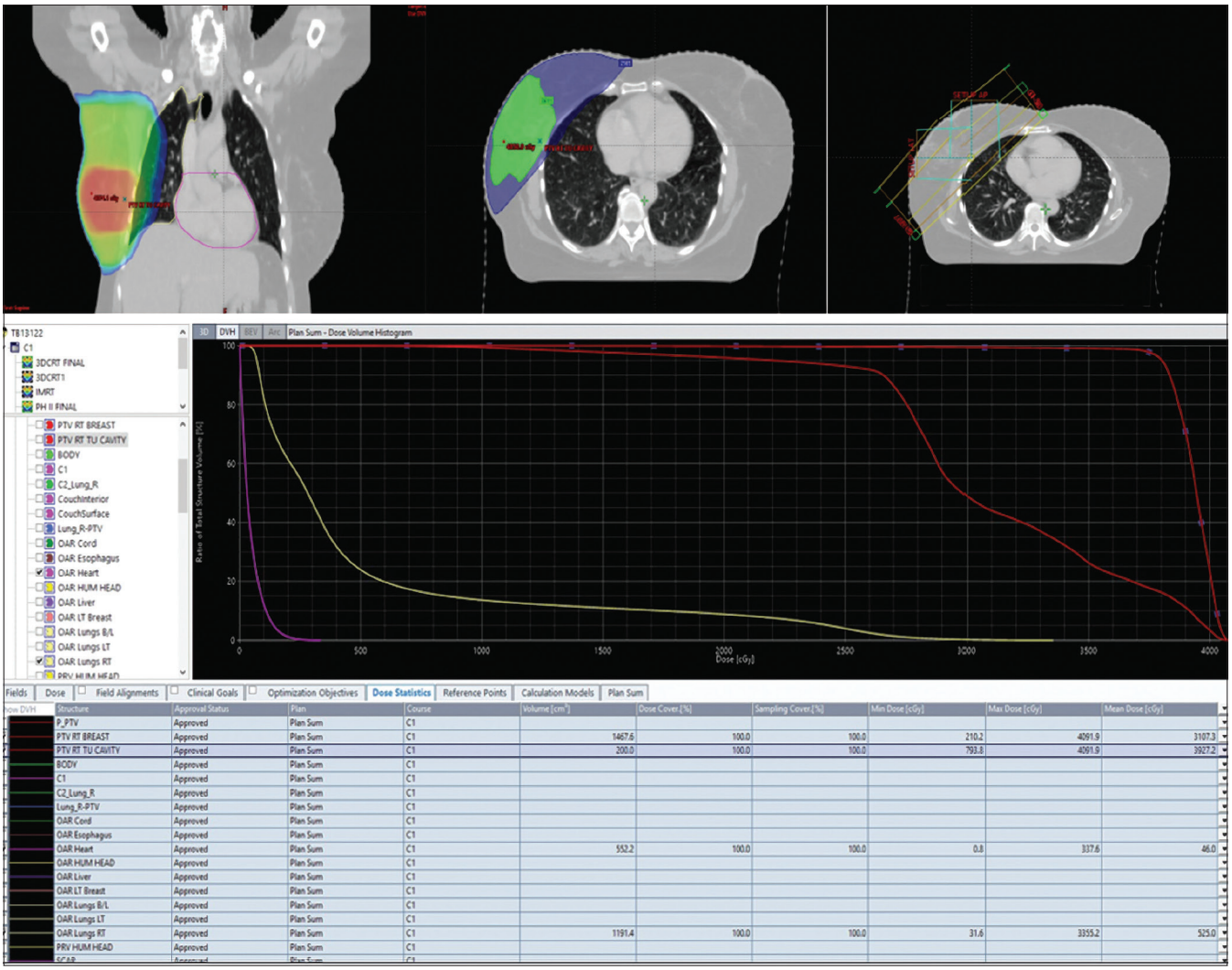

Figure 1: Planning of a 54 year old lady, carcinoma right breast, cT2N0, post BCS, pT2N0, HR – positive, Her2neu – negative, receiving adjuvant radiation treated with extreme hypo fractionation. Figure represents the target volumes both clinical target volume (CTV) whole breast and tumour bed, dose colour wash, planning tangential placement, and dose volume histogram

Feasibility

Out of 25 patients receiving treatment, 12 (48%) patients were treated with the 3DCRT technique, 5 (20%) patients were treated with the IMRT technique, 7 (28%) patients were treated with the VMAT technique and 1 (4%) patient required hybrid 3DCRT + VMAT technique-based treatment [Table 5]. All the patients achieved the target volume constraints of V95% more than or equal to 90%, 21 patients achieved V105% ≤7%, and all the patients achieved Dmax <110%. Dose constraints for the heart were achieved in all the patients. Dose constraints for lung were achieved in 20 patients with a variation around 1%–3% in the rest of patients, which is still within acceptable limits.

Acute skin toxicities

Patients were evaluated for acute toxicities during radiation and up to 3 months after completion of treatment. Acute skin toxicities were graded as per CTCAE version 3.0 criteria (Common Terminology Criteria for Adverse Events (CTCAE) and it is developed by National Cancer Institute under U.S department of Health and Human Services). Majority of patients did not have any noted skin toxicities during radiation [Table 6]. Skin toxicity started 2 weeks postradiation and lasted for 2–3 weeks. 20 (80%) patients had grade 1 acute skin toxicities during and within 4 weeks after completion of radiation. Two patients (8%) had grade 0 and 3 (12%) had grade 2 toxicities, respectively [Figure 2]. Patient-reported adverse effects were reported by five patients as per the EORTC QLQ BR23 questionnaire in the form of breast swelling (1 patient), breast pain (3 patients), skin problems (3 patients), which was mild to moderate. All

Table 3: Organs at risk dose constraints

Ipsilateral lung	Heart
V8<15% (optimal)	V1.5<30%
V8<17% (mandatory)	V7<5%

Figure 2: Clinical images of 2 patients (patient 1 post breast-conserving surgery and patient 2 post mastectomy) who received adjuvant radiation to whole breast and chest wall at 1 month post radiation and 3 months post radiation

Table 4: Patient characteristics

Pt. No.	Site	Type of RT	RT Technique	V95%>/=90%	V105%</=7%	V107%>/=2%	Dmax</=110%	Lungs V8<17%	Heart V1.5<30%	Heart V7<5%
1	Right	Chest Wall	VMAT	95	1.8	0	105.7	17	25	0.16
2	Right	WBRT + Boost	3DCRT	95	4.7	1.61	109	10	2	0
3	Left	WBRT + Boost	3DCRT	95	12	1.5	110	18	23	5
4	Right	Chest Wall	3DCRT	98	5	1	108	18	25	0
5	Right	WBRT + Boost	3DCRT	96.4	8	2	110	20	5	0
6	Left	WBRT + Boost	3DCRT	94	10	2	109	15	21	4.7
7	Left	Chest Wall	IMRT	96	5	0.3	108	13.2	25	0.5
8	Left	Chest Wall	3DCRT	92	15	2	109	12	25	5
9	Left	WBRT + Boost	3DCRT	94.5	12	2	108	5	25	3
10	Right	WBRT + Boost	IMRT	97	1.8	0.02	107	15	24	0.97
11	Right	WBRT + Boost	IMRT	99	1.8	0.8	109	15	24	0
12	Right	WBRT + Boost	IMRT	98.5	2.2	0.77	108	16	19.4	0.8
13	Left	WBRT + Boost	3DCRT + VMAT	93	5	0.9	108	17	25.5	5
14	Right	WBRT + Boost	VMAT	97	2.8	0.1	107	14	12	0
15	Right	WBRT + Boost	3DCRT	98	3.3	1.2	109	14	3.8	0
16	Right	WBRT + Boost	VMAT	99	4	0.0008	107	12.5	10	0
17	Right	Chest Wall	VMAT	99	8	0.0003	107	13	14	0
18	Left	WBRT + Boost	3DCRT	98	5	2	109	15	18	3
19	Right	Chest Wall	VMAT	97	6	2	108	17	18	2
20	Left	WBRT + Boost	VMAT	92	7	2	109	17	25	3
21	Right	WBRT + Boost	3DCRT	98	6.7	2	109	18	8	0
22	Left	WBRT + Boost	IMRT	97	8	2.5	109	17	25	3
23	Right	WBRT + Boost	3DCRT	98	6	1.5	108	16	22	1
24	Left	WBRT + Boost	VMAT	99	7	2	109	18	25	4.5
25	Right	WBRT + Boost	3DCRT	96	3.8	1.8	109	15	21	0

Table 5: Dosimetry indices of patients included in the study

	No. of Subjects	Percentage
Age (Years)		
</=40	3	12.00%
41-60	21	84.00%
61 & above	1	4.00%
Total	25	
Stage		
T2N0	17	68.00%
T2N1A	4	16.00%
T3N0	4	16.00%
Total	25	
Molecular Status		
All Positive	4	16.00%
ER + PR Positive	9	36.00%
Only HER2 Positive	2	8.00%
All Negative	10	40.00%
Total	25	
Chemo		
Given	21	84.00%
Not Given	4	16.00%
Total	25	
Hormonal Therapy		
Given	13	52.00%
Not Given	12	48.00%
Total	25	
Radiation Dose		
Whole Breast + Boost	16	64.00%
Chest wall	9	36.00%
Total	25	
Performance Score		
Grade 0	9	36.00%
Grade 1	16	64.00%
Total	25	
IDC Grade		
Grade 2	5	20.00%
Grade 3	20	80.00%
Total	25	

Table 6: Acute skin toxicities noted

Acute skin toxicities	Number of subjects (%)
Grade 0	2 (8.0)
Grade 1	20 (80.0)
Grade 2	3 (12.0)
Total	25

side effects were self-limiting and they subsided within 1 month after the completion of the radiation

Discussion

We attempted to evaluate the feasibility of 1-week extreme hypofractionated regimen in breast cancer in Indian scenario. We were able to achieve all planning parameters in compliance with Fast forward planning protocol in our study population. 3DCRT, IMRT, VMAT based plans were generated for all the patients and the best plan out of three in terms of target coverage and OAR control was used to treat the patient. There was no difference between the need for advanced techniques like IMRT or VMAT based on the laterality of the tumor. The need for advanced techniques depended mainly on the volume of the target and OARs, the shape and angulation of the chest wall.

FAST FORWARD TRIAL showed a better late normal tissue effects in 26 Gy arm compared to 27 Gy arm. The alpha-beta estimate in Fast Forward trial was 2.3 which gave an EqD2 of 45.2 Gy and 48.2 Gy for 26 Gy and 27 Gy arm, respectively. However, various studies showed varied alpha-beta values for breast ranging from 2 to 4 and we consider an alpha-beta of 3 for breast at our institute. An alpha – beta 3 gives an EqD2 of 42.6 for 26 Gy dose and 45.4 Gy for 27 Gy dose. In order to achieve an EqD2 of 45 Gy, we have chosen to deliver 27 Gy in 5 fractions.

Fast forward trial used a sequential boost of 10–16 Gy in conventional fractionation with photons or electrons. This adds an additional 5–8 days to the overall treatment time. Taking this into consideration, we used a sequential tumor bed boost of 11 Gy in 3 fractions @ 3.67 Gy/fraction (EqD2-14.6 Gy, alpha-beta-3), thereby reducing the overall treatment time to 8 days. The tumor bed boost was delivered using photons as per our institutional protocols. The long-term results of the ongoing HYPORT-Adjuvant[15] a phase 3 Randomized control trial evaluating feasibility, safety of simultaneous integrated tumor boost along with 1 week irradiation in adjuvant treatment of breast cancer may help in further reducing this treatment time.

Acute toxicities were analyzed using CTCAE version 3.0 (Common Terminology Criteria for Adverse Events (CTCAE) and it is developed by National Cancer Institute under U.S department of Health and Human Services) and majority of our study population had Grade 1 skin toxicities during and 1-month postradiation. As the duration of radiation is less and the breast is a late-reacting tissue, no major skin reactions were observed during the treatment. Patients reported side effects during week 2 and week 3 after radiation. Almost 80% of the patient population had Grade 1 skin reactions at 1-month follow-up. The severity of reactions was higher in patients who received whole breast radiation with boost compared to chest wall radiation. Two patients had grade 2 reactions in the form of wet desquamation, which developed in 3rd week postradiation and subsided for 2 weeks. None of the patients in the study population had Grade 3 or Grade 4 reactions.

In the Fast Forward trial sub-study of acute toxicities[16] conducted on 194 patients in 2011–2013, 63% (n = 26) of patients in 27 Gy arm (n = 53) has grade I acute toxicity and 27% of patients (n = 11) has grade II Acute toxicity. Only 1 (2%) patient had grade III toxicity. In our study population, we had no grade 3 toxicities reported and grade 1 toxicities are considerably higher compared to Grade II toxicities. This might be due to changes in skin hygiene protocols followed by the patients and climate conditions. These toxicities were equal in both 26 Gy and 27 Gy arms in the Fast forward trial; however, late normal tissue effects were higher in 27 Gy arm compared to 26 Gy arm.

These are some of the limitations of our study. The sample size of our study is small, and further larger studies may be needed to come to fair or reasonable conclusions. This is a single-arm study with no comparative arm. There is no head-to-head comparison with three weekly regimens, which is the current standard of care. The short follow-up period of 3 months, allows us to evaluate acute toxicities, but longer follow-up is needed to assess the long-term toxicity and safety profile. Longer follow-up and a larger population are required to assess the local control and survival outcomes. A further follow-up study in these cohort of patients to evaluate the late outcomes, long-term quality of life, and tumor control rates will be done and updated.

At the time of this study, our institute was not equipped with deep inspiration breath-hold (DIBH), so we treated our patients with strict daily imaging and positioning. However, we did not have any difficulty in achieving the desired minimal cardiac and lung doses, and as we followed strict daily image guidance protocol, we could manage the study without the need for DIBH in our patients. However, if DIBH is available, we would advise to treat these patients under DIBH with strict image guidance.

Conclusion

One-week hypofractionated radiation therapy for breast cancer is feasible in the Indian patient population. The dose constraints can be achieved with meticulous planning, daily on-couch image guidance, and usage of advanced techniques such as IMRT, VMAT, and hybrid techniques whenever necessary. The treatment schedule is well tolerated. Majority of acute toxicity developed 2–4 weeks posttreatment and resolved in 2–3 weeks. Majority of our patients experienced Grade 1 toxicity. None of our study patients experienced grade 3–4 toxicity. Few patients reported mild to moderate breast symptoms as per the EORTC breast cancer-specific quality of life questionnaire immediately after completion of radiation therapy, which subsided within 1 month. Hence, we conclude that 1-week hypofractionated radiation therapy in breast cancer is safe, feasible, and logistically beneficial in the Indian population.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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