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Original Article

Adverse Events and their Management Associated with Radiation Therapy in Breast Cancer Treatment: A Prospective Observational Study

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ABSTRACT

Background: Radiation therapy is an important treatment modality of cancer therapy. Especially for Breast Cancer it stands as primary approach of the treatment along with chemotherapy. However, radiation therapy is associated with certain adverse events which may cause significant discomfort to patients and may impact on their day-to-day activities. The objective of the study is to study the pattern of radiation related adverse events and their management in patients who are on radiation therapy or chemo-radiation therapy in breast cancer. **Materials and Methods:** A prospective observational study was conducted over one year at Bharath Hospital and Institute of Oncology, Mysore, following ethical approval from the Institutional Ethics Committee. The study evaluated radiation-induced adverse events in breast cancer patients using MedDRA codes and RTOG grading. Patients receiving radiation alone or with chemotherapy were included, while those without cancer or receiving only chemotherapy, targeted, or hormonal therapy were excluded. Data were obtained from treatment charts, radiation cards, laboratory reports, and patient interviews. Adverse events were identified, confirmed with oncologists, graded as per RTOG criteria, and analysed for treatment patterns and management outcomes. **Results:** Among 315 female breast cancer patients, most were aged 51-60 years (51.7%) with invasive ductal carcinoma (62.2%) as the major subtype. ER positivity was seen in 46%, and early-stage disease (Stage 0-I) in 60.3%. Adjuvant therapy predominated (60.9%), with EBRT (78.7%) as the main modality. Common radiation-related adverse events were fatigue (73.9%), dermatitis (42.8%), breast pain/swelling (31.1%), nausea and gastritis (16.2% each), hyperpigmentation (8.6%), and pneumonitis (6.0%). Most were mild to moderate (RTOG 1-2) and managed supportively. However, 18-35% of cases, mainly fatigue and dermatitis, lacked intervention, indicating a need for improved supportive and pharmacist-led care. **Conclusion:** Radiation therapy is well tolerated in breast cancer patients, but proactive, multidisciplinary care and continuous monitoring are essential to manage adverse events and optimize patient outcomes.

Keywords: Adverse Event, Breast Cancer, MedDRA Code, Radiation therapy, RTOG.

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INTRODUCTION

Breast Cancer (BC) is recognized as the most commonly diagnosed neoplasm among female populations globally, with more than 2 million new cases documented in the year 2020. Where, the risk measurement associated with BC include both modifiable and non-modifiable factors, with nearly eighty percent of cases presenting in individuals aged over 50 years. The prognostic outcomes are significantly affected by both the stage of the cancer and its specific molecular subtype (Lukasiewicz *et al.*, 2021). The diagnosis of the BC is done by physical examination, breast imaging (mammography) and tissue biopsy, whereas the treatment options currently used in clinical practice includes surgery, chemotherapy, Radiation Therapy (RT), hormonal therapy, and immunotherapy are being used (Watkins 2019; Waks and Winer 2019). For non-metastatic breast cancer surgery considered to be the most effective treatment and also, the chemotherapy-based preoperative systemic therapy decreases the tumour mass, prevents removal of axillary lymph nodes and conserve breast tissue. However, in metastatic BC, surgery is the first choice of treatment chemotherapy, RT, targeted therapy, immunotherapy, and hormonal therapy are used as palliative therapies (Cardoso *et al.*, 2019; Senkus and Lacko, 2017). RT is one of the palliative therapies and reduces the relapse rate by fifty percent, where external beam radiation, brachytherapy,

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or both are being used (Litiere *et al*., 2012; Tang *et al*., 2018). Many studies reported that the comparison of various RT in adjuvant therapy as Whole Breast Irradiation (WBI), Partial Breast Irradiation (PBI), Accelerated partial-breast irradiation (APBI) and brachytherapy resulted in local relapse rate of 4.4 to 4.5% (Wang and Wu 2023). However, the External Radiation Therapy (ERT) or External Beam therapy (EBT) can be used for irradiating the specific cancer tissues, where a low beam of protons or photons or electrons are used to kill tumour tissue and had been associated with promising results in BC, Prostate cancer etc. (Hanks 1986). The adverse effects associated irradiating the breast tissue includes major coronary events such as atherosclerosis and even more worsening the condition in cardiovascular disease patients (Darby 2013). pneumonitis in patients receiving nodal RT worsened by concomitant use of taxanes (Whelan *et al*., 2015; Brown *et al*., 2015). fibrosis of the irradiated breast tissue within 4-12 months of the RT (Williams *et al*., 2019). others including lymphadenoma, rib fracture and other RT induced secondary malignancies such as lung, and oesophageal cancers (Gross *et al*., 2019; Pierce *et al*., 1992; Ye *et al*., 2015). Management of RT associated adverse effects is carried out by maintaining oral hygiene, topical analgesics, dietary modification, opioid analgesics, chlorhexidine rinses, enteral tube feeding in severe cases (Majeed and Gupta 2025). Thus, this study aimed to assess, report and management of Adverse events associated with Radiation therapy or Chemo-radiation therapy in breast cancer treatment.

METHODOLOGY

Study Design and Study Settings

This prospective observational study was conducted in accordance with ethical guidelines and IEC at Bharath Hospital and Institute of Oncology, Mysore, over a period of one Year. It aimed to assess radiation-related adverse events in breast cancer patients, using MedDRA codes for events, RTOG grades for severity, and evaluating their management during radiation therapy for Breast cancer treatment.

Study Participants Criteria

The study participants were selected based on specific inclusion and exclusion criteria. The inclusion criteria included patients receiving radiation therapy for breast cancer treatment, patients receiving radiation therapy and chemotherapy concomitantly, On the other hand, the exclusion criteria included patients without cancer, patients who are mentally challenged, and patients receiving no RT. By applying these criteria, the study aimed to ensure that the participants were relevant to the research question and that the results would be applicable to the targeted population.

Sampling Techniques and Sample Size Calculation

A prospective random sampling method was applied, and the sample size was calculated to enrol minimum of 312 participants, based on a 5% margin of error, 50% population proportion, 0.05 precision, and a 95% confidence interval, considering a 28% prevalence of breast cancer in India (Sathishkumar *et al*., 2024).

Data Collection and Data Analysis

Data were collected from various sources, including patient records, radiation charts, and laboratory reports, to obtain details on demographics, diagnosis, treatment plans, radiation dose and frequency, and medical history (File: S1). Patient interviews captured treatment experiences and adverse events, while discussions with oncologists and other healthcare professionals provided additional clinical insights and then Data is entered in to Microsoft Excel and analysed using SPSS v25.0 (IBM). Categorical variables were summarized as frequencies and percentages.

Study Procedure

Patients monitored daily for radiation-related adverse events. Identified events were verified with radiation oncologists to ensure accuracy and graded the events based on Radiation Therapy Oncology Group (RTOG) criteria. Management approaches and outcomes were reviewed to evaluate treatment effectiveness and highlight potential areas for improvement.

Ethical Approval

The study was conducted in accordance with Institutional Human Ethics Guideline. Duly signed of written Informed Consent form (File: S2) by patients in which are involved with no patient's interventions. Ethical approval was obtained from the Institutional Ethics Committee, Bharath Hospital and Institute of Oncology (BHIO), Mysore. (File: S3).

RESULTS

Demographics Characteristics

A total of 315 breast cancer cases were reviewed in this study, all of which involved female patients. The largest proportion belonged to the 51-60 year age group (51.74%), followed by 40-50 years (28.25%). Only 6.05% of patients were younger than 40, while 13.96% were aged between 61 and 70 years. With respect to histopathology, invasive ductal or carcinoma was identified as the leading subtype (62.22%). Invasive lobular carcinoma accounted for 24.44%, and medullary breast carcinoma for 13.33%.

An evaluation of hormone and genetic receptor patterns showed that nearly half of the tumors were estrogen receptor positive (46.03%). A smaller fraction (3.80%) were estrogen receptor negative. Combined ER and PR positivity was recorded in 23.39%, while HER2 positivity occurred in 15.55% of cases. Tumors with triple receptor positivity represented 3.17%, whereas

triple-negative cancers made up 5.39%. Additionally, 2.53% of patients had BRCA1 positivity.

When staged according to the TNM classification, the majority were detected in early disease (Stage 0-I, 60.3%). Approximately 21.3% were diagnosed with Stage II disease, while 8.23% had Stage III involvement. A notable 13.3% of patients were already at the metastatic stage (Stage IV) at presentation.

In summary, the study highlights that most patients were middle-aged women, with IDC being the most common histological type, and a predominantly hormone receptor-positive profile. Although many were diagnosed in the early stages, a considerable share of cases presented at an advanced or metastatic stage (Table 1).

Treatment Modalities

Among 315 breast cancer patients, adjuvant therapy was the most frequently employed treatment approach (60.95%), followed by neoadjuvant (25.71%) and palliative therapy (13.33%). Within the adjuvant setting, radiation therapy alone was most common, while chemoradiation and radiation combined with targeted or hormonal therapy were also utilized. Similar patterns were observed in neoadjuvant and palliative groups, with radiation remaining the dominant modality.

External Beam Radiation Therapy (EBRT) constituted the principal technique, administered in 78.73% of cases, whereas brachytherapy was used in 21.26%. Chemotherapy regimens most often included AC+Paclitaxel (Adriamycin, Cyclophosphamide, and Paclitaxel), EC (Epirubicin and Cyclophosphamide), TC (Docetaxel and Cyclophosphamide), and TAC (Docetaxel, Doxorubicin, and Cyclophosphamide). Additional agents such as Capecitabine, Olaparib, and Eribulin were prescribed selectively in advanced or resistant cases. Targeted therapies comprised Trastuzumab and Pertuzumab, while hormonal agents included Fulvestrant, Letrozole, and Anastrozole (Table 1).

MedDRA Code and RTOG Grade of Radiation Therapy Adverse Events and their Management

In the present study involving 315 breast cancer patients, the most frequently reported radiation-associated adverse event was fatigue (73.96%), followed by dermatitis or skin reactions (42.85%), breast pain and swelling (31.11%), nausea (16.19%), gastritis (16.19%), hyperpigmentation (8.57%), and radiation pneumonitis (6.03%).

Fatigue, predominantly classified as RTOG Grade 1 (50.79%), was effectively managed with supportive fluid therapy such as 5% dextrose and DNS, while higher grades required multivitamin supplementation. Dermatitis was mainly of Grade 2 severity (60.74%) and responded well to topical Metronidazole with Gentian violet paint. Grade 3 cases were treated with Diclofenac and Lignocaine gel. Breast pain and swelling were primarily mild (Grade 1, 58.16%) and controlled with Diclofenac gel, whereas moderate to severe grades required Tramadol, Paracetamol, and Prednisolone combinations.

Nausea (16.19%) occurred across Grades 1-3 and was treated with Domperidone or Ondansetron depending on severity. Hyperpigmentation, mainly of Grade 3 (55.55%), was managed

Table 1: Distribution of Demographic Details and Clinical Parameters.

Variables	Frequency	Precentage
Age		
29 to 39 years	19	6.05%
40 to 50 Years	89	28.25%
51 to 60 Years	163	51.74%
61 to 70 Years	44	13.96%
Gender		
Male	0	0%
Female	315	100%
Type of Breast Cancer		
IDC/IFDC	196	62.22%
ILC	77	24.44%
MBC	42	13.33%
Details of Hormonal Receptor		
ER +ve	145	46.03%
ER -ve	12	3.80%
ER/PR +ve	74	23.39%
HER2 +ve	49	15.55%

Variables	Frequency	Precentage	
ER+PR+HER +ve (Tripple +ve)	10	3.17%	
ER+PR+HER -ve (Tripple -ve)	17	5.39%	
BRCA1 +ve	8	2.53%	
Stage of Breast Cancer			
Stage	TNM	Number	%
Stage 0 (DCIS)	Tis N0 M0	56	17.77%
Stage IA	T1 N0 M0	89	28.26%
Stage I B	T1N1mi M0	45	14.28%
Stage II A	T1 N1M0	05	1.58%
	T2 N0 M0	03	0.95%
Stage II B	T2 N1 M0	31	9.84%
	T3 N0 M0	27	8.57%
Stage III A	T2 N2 M0	6	1.90
	T3 N2 M0	7	2.22
Stage IIIB	T4 N2 M0	9	2.85%
Stage IIIC	T4 N3 M0	4	1.26%
Stage IV	T4 N2 M1	19	6.03%
	T4 N3 M1	23	7.30

Treatment Modalities				
Types of Therapy	Radiation Therapy	Chemoradiation Therapy	Radiation with Targeted/ Hormonal	Total n=315
Adjuvant Therapy	95	69	28	192
Neo Adjuvant Therapy	38	31	13	81
Palliative Care	15	19	8	42

Type of Radiation Therapy Used		
External beam radiation therapy	248	78..73%
Brachy therapy	67	21.26%

Type of Regimens Used	
Regimens	Type of Therapy
AC+ PACLI (Adriamycin, Cyclophosphamide and Paclitaxel)	Chemotherapy
EC (Epirubicin, Cyclophosphamide)	
TC (Docetaxel and Cyclophosphamide)	
TAC (Docetaxel, Doxorubicin, Cyclophosphamide)	
PACLI (Paclitaxel)	
CARBO Pacli Carboplatin+ Paclitaxel)	
Capecitabine	
Olaparib	
ERIBULIN	
TRASTU (Trastuzumab)	Targeted Therapy
Pertuzumab	
Fulvestarant	Hormonal Therapy
Letrozole	
Anastrozole	

Table 2: MedDRA Code and RTOG Grade of Radiation Therapy Adverse Events and their Management.

MedDRA Code	Event	Number N=315/%	RTOG Grade	n (%)	Treatment	n (%)	No treatment received n (%)
10016256	Fatigue	233 (73.96)	1	160 (50.79)	5% Dextrose	131 (81.87)	29 (18.12)
			2	52 (22.31)	DNS	39 (75.0)	13 (25.0)
			3	16 (6.86)	DNS + Multivitamin	16 (100)	0
			4	5 (2.14)	RL + DNS + Multivitamin	5 (100)	0
10037867	Dermatitis/ Change in Skin	135 (42.85)	1	32 (23.70)	Gentian violet Paint	25 (78.12)	7 (21.87)
			2	82 (60.74)	Metronidazole + Gentian violet Paint	71 (86.58)	11 (13.41)
			3	21 (15.55)	Diclofenac and lignocaine gel	21 (100)	0
10006477	Breast Pain and Swealing	98 (31.11)	1	57 (58.16)	Diclofenac Gel	37 (64.91)	20 (35.08)
			2	29 (29.59)	Diclofenac + Lignocaine gel Tab. Aceclofenac	29 (100)	0
			3	12 (12.24)	Diclofenac + Lignocaine Gel, Tab. Tramadol + Paracetamol + Prednisolone	12 (100)	0
1002813	Nausea	54 (16.19)	1	23 (42.59)	Tab. Domperidone	18 (78.26)	5 (21.73)
			2	18 (33.33)	Inj. Ondansetron	15 (83.33)	3 (16.66)
			3	13 (24.07)	Inj. Ondansetron	13 (100)	0
10020673	Hyperpig-mentation	27 (8.57)	1	7 (25.92)	Hydroquinone USP + Tretinoin USP + Fluocinolone Acetonide	4 (57.14)	3 (42.85)
			2	5 (18.51)	Hydroquinone USP + Tretinoin USP + Fluocinolone Acetonide	5 (100)	0
			3	15 (55.55)	Kojic Acid Dipalmitate + Arbutin + Liquorice, Mulberry Extract+ Tetrahydrocurcumin + Artocarpus Extract	11 (73.33)	4 (26.66)
10019350	Gastritis	51 (16.19)	1	14 (27.45)	Tab. Pantoprazole	9 (64.28)	5 (35.71)
			2	17 (33.33)	Tab. Pantoprazole + Metoclopramide	13 (76.47)	4 (23.52)
			3	12 (23.52)	Tab. Pantoprazole, Susp. Oxethazine, Mg $(OH)_2$, Al $(OH)_3$	12 (100)	0
			4	8 (15.68)	Inj. Pantoprazole, Susp. Oxethazine, Mg $(OH)_2$, Al $(OH)_3$	8 (100)	0
10020405	Radiation Pneumonitis	19 (6.03)	1	14 (73.68)	Tab. Amifostine	14 (100)	0
			2	5 (26.31)	Tab. Methyl Prednisolone, Tab. Clarithromycin	5 (100)	0

using topical agents containing Hydroquinone, Tretinoin, Fluocinolone acetonide, Kojic acid, and plant-based extracts. Gastritis was noted in 16.19% of patients, with Pantoprazole, Metoclopramide, and antacid suspensions (Oxethazine, Magnesium hydroxide, Aluminum hydroxide) used according to grade. Radiation pneumonitis (6.03%), mostly of Grade 1, was managed with Amifostine, while higher grades were treated with Methylprednisolone and Clarithromycin.

This study found the majority of adverse events were mild to moderate (RTOG Grades 1-2) and managed successfully with supportive or symptomatic therapy. Only a small proportion of patients required escalation to pharmacological interventions for Grade 3-4 toxicities, indicating that radiation therapy was generally well tolerated in this cohort (Table 2).

Interventions and Supportive Care in Untreated Adverse Events

Evaluation of patients lacking management for radiation-related toxicities revealed notable care deficiencies. Approximately 18-25% with fatigue, 13-22% with dermatitis, and about 35% experiencing breast pain or swelling did not receive therapy. Likewise, 16-35% of those with nausea or gastritis and up to 43% with hyperpigmentation were left untreated. In contrast, all radiation pneumonitis cases were properly addressed. The highest gaps occurred in fatigue and breast pain, highlighting the need for prompt assessment and affordable supportive measures. Enhancing pharmacist-driven and team-based care, alongside standardized management guidelines, could reduce untreated cases and improve patient outcomes (Table 2).

DISCUSSION

Most breast cancer patients receiving radiation therapy were middle-aged women with invasive ductal carcinoma and hormone receptor-positive tumors, consistent with previous reports by (DeSantis *et al.*, 2019; Sung *et al.*, 2021). Radiation therapy remains vital for disease control and survival improvement (Darby *et al.*, 2013). Though its benefits are often limited by treatment-related toxicities. Fatigue and dermatitis were the most common adverse events, in line with earlier studies (Schnur *et al.*, 2011; Kole and Moran 2017). Most were mild to moderate (RTOG Grades 1-2) and effectively managed with supportive care, indicating advances in radiation techniques. However, some patients did not receive appropriate management for fatigue, skin reactions, or breast pain, suggesting a need for improved follow-up and supportive care. Active involvement of pharmacists and nursing staff, as emphasized by (Holle 2020), may enhance timely toxicity management. Less frequent events such as gastritis, hyperpigmentation, and pneumonitis were also observed, with pneumonitis requiring close monitoring due to respiratory risk, as noted by (Palma *et al.*, 2013). Therefore, systematic toxicity grading, early intervention, and multidisciplinary monitoring can improve radiation tolerability and patient quality of life.

CONCLUSION

Radiation therapy in breast cancer patients was well tolerated, with most toxicities being mild or moderate and effectively managed through supportive measures. Patients on radiation and chemo radiation therapy need careful follow up to identify radiation related negative outcomes. However, the presence of untreated or inadequately addressed adverse events highlights the need for proactive supportive care. Integrating multidisciplinary interventions particularly pharmacist-led management can strengthen symptom control, improve treatment adherence and enhance the patient's overall quality of life. Continuous toxicity monitoring and patient counselling should be integral parts of radiation therapy programs.

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ABBREVIATIONS

MedDRA: Medical Dictionary for Regulatory Activities; **RTOG:** Radiation therapy oncology Group; **BC:** Breast Cancer; **EBRT:** External Beam Radiation Therapy; **CT:** Chemotherapy; **RT:** Radiation Therapy; **IDC:** Invasive Ductal Carcinoma; IFDC: Infiltrating Ductal Carcinoma; **ILC:** Invasive Lobular Carcinoma; **MBC:** Metastatic Breast Cancer; **QoL:** Quality of Life; **TNM:** Tumor Node Metastatic; **PR:** Progesterone Receptor; **ACT:** Adjuvant Chemotherapy; **NACT:** Neoadjuvant Chemotherapy; **ER:** Estrogen Receptor; **SPSS:** Statistical Package for Social Sciences; **GEMCI:** Gemcitabine; **CARBO:** Carboplatin; **PACLI:** Paclitaxel; **AC:** Adriamycin, Cyclophosphamide; **TC:** Docetaxel and Cyclophosphamide; **FAC:** Fluorouracil, Doxorubicin, and Cyclophosphamide; **FEC:** Fluorouracil, Epirubicin, and Cyclophosphamide; **TRASTU:** Trastuzumab.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVALS

The study was conducted in accordance with the Ethical guidelines for biomedical research on human participants without any interventions, after obtaining approval from the Institution Ethics Committee (IEC) vide IEC No: ECM/09/23

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study.

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