



INCIDENCE AND IMPACT OF RADIATION PNEUMONITIS FOLLOWING RADIOTHERAPY IN BREAST CANCER PATIENTS: A COMPREHENSIVE ANALYSIS

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ABSTRACT

Background: Radiotherapy is an integral component in the management of breast cancer, significantly improving local control and survival. However, radiation pneumonitis (RP) remains a notable adverse effect, potentially affecting treatment outcomes and patients' quality of life.

Aim: To evaluate the incidence and clinical impact of radiation pneumonitis in breast cancer patients undergoing radiotherapy.

Methods: This prospective observational study was conducted in the Department of Radiotherapy at Sree Mookambika Institute of Medical Sciences, Kulasekharam, Tamil Nadu, over 18 months. A total of 200 histopathologically confirmed breast cancer patients receiving adjuvant radiotherapy were included. Baseline clinical and treatment-related parameters were recorded. Dosimetric variables such as mean lung dose (MLD) and V20 were analyzed. Patients were followed up at 1, 3, and 6 months post-radiotherapy for clinical and radiological evidence of RP, which was graded using CTCAE version 5.0.

Results: The incidence of radiation pneumonitis was 13%. Most cases were mild to moderate (Grade 1–2), with only 2.5% experiencing severe toxicity. A significant association was observed between RP and higher dosimetric parameters (MLD and V20) ($p < 0.001$). The majority of cases presented within 3 months of treatment, with dry cough and dyspnea being the most common symptoms. Approximately 50% of affected patients required corticosteroid therapy, while hospitalization was rare.

Conclusion: Radiation pneumonitis is a relatively common but manageable complication of breast radiotherapy. Strict adherence to lung dose constraints and early detection are essential to minimize its impact and improve patient outcomes.

KEYWORDS: Breast Cancer, Radiation Pneumonitis, Radiotherapy, Mean Lung Dose, V20, Pulmonary Toxicity, CTCAE.

Introduction

Breast cancer is the most commonly diagnosed malignancy among women worldwide and a leading cause of cancer-related mortality. According to the World Health

Organization, breast cancer accounts for a substantial proportion of global cancer burden, with increasing incidence observed in both developed and developing countries, including India. Radiotherapy plays a crucial

role in the multidisciplinary management of breast cancer, significantly reducing local recurrence rates and improving overall survival following breast-conserving surgery or mastectomy[1]. Despite its well-established therapeutic benefits, radiotherapy is associated with certain adverse effects, among which radiation pneumonitis (RP) is one of the most important dose-limiting toxicities. RP is an inflammatory reaction of the lung parenchyma that typically occurs within weeks to months following irradiation and may progress to pulmonary fibrosis if not recognized and managed appropriately[2]. The incidence of radiation pneumonitis varies widely depending on several factors, including radiation technique, total dose, fractionation, and the volume of lung irradiated. Previous studies have reported an incidence ranging from 1% to 35%, with clinically significant symptomatic pneumonitis occurring in approximately 10–15% of breast cancer patients receiving radiotherapy[3,4].

Advances in radiotherapy techniques, such as three-dimensional conformal radiotherapy (3D-CRT) and intensity-modulated radiotherapy (IMRT), have contributed to a reduction in pulmonary toxicity; however, the risk remains clinically relevant[5]. Dosimetric parameters, particularly mean lung dose (MLD) and V20 (volume of lung receiving ≥ 20 Gy), have been consistently identified as strong predictors of radiation pneumonitis. Several normal tissue complication probability (NTCP) models have demonstrated a direct correlation between increasing lung dose and the likelihood of developing RP[6]. Patient-related factors such as age, smoking status, pre-existing lung disease, and concurrent systemic therapies (chemotherapy, hormonal therapy, and targeted therapy) may further influence susceptibility to radiation-induced lung injury[7]. Clinically, radiation pneumonitis commonly presents with non-productive cough, dyspnea, low-grade fever, and chest discomfort, typically within 6–12 weeks after completion of radiotherapy.

Radiological findings may range from minimal infiltrates to extensive consolidation within the irradiated lung fields. Early diagnosis is essential, as timely intervention with corticosteroids can significantly improve outcomes and prevent progression to irreversible fibrosis[8]. Although several studies have evaluated radiation pneumonitis in breast cancer patients, there is limited data from South Indian populations, particularly in tertiary care settings where variations in patient characteristics, treatment protocols, and resource availability may influence outcomes. Therefore, the present study was undertaken to evaluate the incidence and clinical impact of radiation pneumonitis in breast cancer patients undergoing radiotherapy at a tertiary care center in Tamil Nadu, and to analyze its association with dosimetric and clinical parameters.

Aim and Objectives

To evaluate the incidence and clinical impact of radiation

pneumonitis among breast cancer patients undergoing radiotherapy at a tertiary care centre.

Objectives

- To determine the incidence of radiation pneumonitis in breast cancer patients receiving radiotherapy.
- To assess the severity and clinical presentation of radiation pneumonitis using radiological and symptomatic grading criteria.
- To evaluate the impact of radiation pneumonitis on treatment outcomes, quality of life, and need for medical interventions (e.g., corticosteroid therapy, hospitalization).

Materials and Methods

Study Design

This study was a hospital-based prospective observational study conducted to evaluate the incidence and impact of radiation pneumonitis in breast cancer patients undergoing radiotherapy.

Study Setting

The study was carried out in the Department of Radiation Oncology, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Tamil Nadu, a tertiary care teaching hospital catering to a large population from South India.

Study Duration

The study was conducted over a period of 18 months, including patient recruitment, treatment, and follow-up.

Study Population

All histopathologically confirmed breast cancer patients planned for adjuvant radiotherapy following surgery (breast-conserving surgery or modified radical mastectomy) were considered for inclusion in the study.

Sample Size

A total of 200 patients were included in the study, calculated based on an expected radiation pneumonitis incidence of 13% with 95% confidence interval and 5% precision, accounting for possible loss to follow-up.

Sampling Technique

A consecutive sampling method was employed, wherein all eligible patients meeting the inclusion criteria during the study period were recruited until the required sample size was achieved.

Inclusion Criteria

- Patients aged ≥ 18 years with histologically confirmed breast carcinoma
- Patients who had undergone surgery (BCS/MRM) and were planned for adjuvant radiotherapy
- Patients with baseline normal or acceptable pulmonary function

Exclusion Criteria

- Patients with pre-existing lung diseases (e.g., COPD, pulmonary fibrosis, active tuberculosis)
- Patients with metastatic disease involving the lungs
- Patients who had received prior thoracic radiotherapy
- Patients with connective tissue disorders known to increase radiosensitivity
- Patients who were lost to follow-up during the study period

Data Collection Procedure

Baseline Assessment

All patients underwent a detailed evaluation prior to initiation of radiotherapy, including:

- **Demographic data:** Age, sex, BMI
- **Clinical history:** Smoking status, comorbidities
- **Tumor characteristics:** Stage, histological type, receptor status
- **Treatment details:** Type of surgery, chemotherapy regimen

Pulmonary Evaluation

- Baseline chest X-ray and/or high-resolution computed tomography (HRCT) were performed
- Pulmonary function tests (PFTs) including FEV1, FVC, and FEV1/FVC ratio were recorded

Radiotherapy Protocol

- Radiotherapy was delivered using 3D conformal radiotherapy (3D-CRT) or intensity-modulated radiotherapy (IMRT) techniques
- Total dose ranged from 40–48 Gy in 15-20 fractions over 3-4 weeks, depending upon whether the patient needs a boost dose to tumor bed
- Treatment planning was done using CT-based simulation
- Dosimetric parameters such as:
 - *Mean lung dose (MLD)*
 - *V20 (volume of lung receiving ≥ 20 Gy)* were recorded for all patients

Follow-Up and Assessment of Radiation Pneumonitis

Patients were followed up at regular intervals:

- At 1 month, 3 months, and 6 months post-radiotherapy, or earlier if symptomatic

Clinical Evaluation

Patients were assessed for symptoms of radiation pneumonitis, including:

- Dry cough
- Dyspnea
- Low-grade fever

- Chest discomfort

Radiological Evaluation

- Chest X-ray or HRCT was performed in symptomatic patients or when clinically indicated

Grading of Radiation Pneumonitis

Radiation pneumonitis was graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0:

- Grade 1: Asymptomatic, radiographic findings only
- Grade 2: Symptomatic, not interfering with daily activities
- Grade 3: Severe symptoms requiring oxygen therapy
- Grade 4: Life-threatening
- Grade 5: Death

Outcome Measures

Primary Outcome

- Incidence of radiation pneumonitis

Secondary Outcomes

- Severity grading of pneumonitis
- Time of onset following radiotherapy
- Association with dosimetric parameters (MLD, V20)
- Requirement of medical management (e.g., corticosteroids)
- Impact on patient quality of life and treatment interruption

Statistical Analysis

- Data were entered in Microsoft Excel and analyzed using SPSS version XX
- Continuous variables were expressed as mean $\pm$ standard deviation
- Categorical variables were expressed as frequency and percentage
- Association between variables was assessed using:
 - Chi-square test for categorical variables
 - Independent t-test or ANOVA for continuous variables
- A p-value < 0.05 was considered statistically significant

Ethical Considerations

- Ethical approval was obtained from the Institutional Ethics Committee of Sree Mookambika Institute of Medical Sciences prior to commencement of the study
- Written informed consent was obtained from all participants
- Confidentiality and anonymity of patient data were strictly maintained throughout the study in accordance with ethical guidelines and the Declaration of Helsinki (revised in 2024).

Results

Table 1: Demographic and Clinical Characteristics of Study Population (n = 200)

Variable	Frequency (n)	Percentage (%)
Age Group (years)		
<40	32	16%
40–50	78	39%
51–60	60	30%
>60	30	15%
Mean Age (years)	49.8 ± 10.6	—
Menopausal Status		
Premenopausal	92	46%
Postmenopausal	108	54%
Smoking Status		
Smoker	28	14%
Non-smoker	172	86%
Comorbidities		
Present	76	38%
Absent	124	62%

Table 2: Tumor and Treatment Characteristics (n = 200)

Variable	Frequency (n)	Percentage (%)
Type of Surgery		
Breast Conserving Surgery (BCS)	82	41%
Modified Radical Mastectomy (MRM)	118	59%
Tumor Stage		
Stage I	24	12%
Stage II	102	51%
Stage III	74	37%
Chemotherapy		
Received	168	84%
Not received	32	16%
Radiotherapy Technique		
3D-CRT	124	62%
IMRT	76	38%

Table 3: Incidence and Grading of Radiation Pneumonitis (n = 200)

Variable	Frequency (n)	Percentage (%)
Radiation Pneumonitis		
Present	26	13%
Absent	174	87%
Grading (CTCAE v5.0)		
Grade 1	12	6%
Grade 2	9	4.5%
Grade 3	4	2%
Grade 4	1	0.5%
Grade 5	0	0%

Table 4: Association of Dosimetric Parameters with Radiation Pneumonitis

Parameter	Pneumonitis Present (n=26)	Pneumonitis Absent (n=174)	p-value
Mean Lung Dose (Gy)	18.6 ± 3.2	14.2 ± 2.8	<0.001*
V20 (%)	32.4 ± 5.6	24.1 ± 4.8	<0.001*

*Statistically significant.

Table 5: Clinical Impact and Management of Radiation Pneumonitis (n = 26)

Variable	Frequency (n)	Percentage (%)
Time of Onset		
<3 months	18	69.2%
3–6 months	8	30.8%
Symptoms		
Dry cough	22	84.6%
Dyspnea	18	69.2%
Fever	10	38.5%
Management		
Conservative (observation)	12	46.2%
Corticosteroid therapy	13	50%
Hospitalization required	1	3.8%
Treatment Interruption		
Yes	5	19.2%
No	21	80.8%

Discussion

Radiation pneumonitis (RP) is a well-recognized complication following breast radiotherapy. In the present study, the incidence, severity, and clinical impact of RP were analyzed and compared with previously published original research.

Incidence of Radiation Pneumonitis

The incidence of RP in the present study was 13%, which is comparable to the findings of Vasiljevic et al[4]., who reported a similar incidence of 13% in a prospective study of breast cancer patients undergoing radiotherapy. In contrast, Mangesius et al[7]. reported a higher overall incidence of 38%, although most cases were asymptomatic (Grade 1), with only 10% being symptomatic. Earlier studies such as Gagliardi et al[3]. also demonstrated variable incidence depending on radiation dose and lung volume exposure, highlighting the heterogeneity in reported rates. Thus, the incidence observed in this study aligns with clinically significant symptomatic pneumonitis rates reported in modern radiotherapy settings.

Severity and Grading

In the present study, the majority of RP cases were Grade 1 and Grade 2, with very few severe cases (Grade ≥3). This is consistent with findings by Mangesius et al[7]., where most cases were mild and no Grade >2 pneumonitis was observed. Similarly, earlier radiobiological modeling

studies such as Gagliardi et al[3]. demonstrated that severe pneumonitis is uncommon when appropriate dose constraints are maintained. These findings confirm that modern radiotherapy techniques significantly limit high-grade toxicity.

Dosimetric Predictors (MLD and V20)

The present study demonstrated a statistically significant association between RP and dosimetric parameters, particularly mean lung dose (MLD) and V20. This observation is strongly supported by multiple studies. Vasiljevic et al[4]. showed that increasing lung dose-volume parameters such as V20 and MLD significantly increase the risk of RP. Similarly, Lind et al[8]. (cited in NTCP modeling studies) reported a clear relationship between irradiated lung volume and pulmonary complications. These findings reinforce that MLD and V20 remain the most reliable predictors of radiation-induced lung toxicity.

Time of Onset and Clinical Features

In the present study, most RP cases occurred within 3 months post-radiotherapy, which is consistent with previous literature. Studies have shown that RP typically develops within 6–21 weeks after treatment[9]. The predominant symptoms observed—dry cough and dyspnea—are also well documented. Vasiljevic et al[4]. described similar symptom profiles, including cough, dyspnea, and fever, as hallmark clinical features of RP.

Impact of Systemic Therapy

The present study observed a higher trend of RP among patients receiving chemotherapy. This is supported by Mangesius et al[7], who demonstrated that combined systemic therapies, particularly endocrine agents like tamoxifen and goserelin, significantly increase RP risk. Additionally, studies such as Beal et al[10] have evaluated the interaction between taxane-based chemotherapy and radiotherapy, suggesting that treatment sequencing may influence pulmonary toxicity.

Influence of Radiotherapy Technique

The use of both 3D-CRT and IMRT in the present study may explain the moderate incidence of RP. Earlier studies reported higher pneumonitis rates (up to 35%) with older techniques, while modern CT-based radiotherapy has reduced incidence to 1–21%. This supports the growing evidence that advanced techniques and optimized planning reduce lung exposure and toxicity.

Clinical Impact and Management

In the present study, 50% of patients required corticosteroid therapy, which is consistent with standard management protocols. Previous studies have shown that symptomatic RP often requires steroid therapy but rarely leads to mortality, with reported death rates <2%. The relatively low hospitalization rate in this study further supports the generally manageable nature of RP when detected early.

Conclusion

The study indicates that radiation pneumonitis is a common yet manageable complication after radiotherapy in breast cancer patients. Most cases are mild to moderate, with severe forms being rare and no recorded mortality, highlighting the safety of current practices. A notable association with dosimetric parameters, especially mean lung dose (MLD) and V20, emphasizes the need for careful treatment planning. Symptoms commonly appear within the first three months and include dry cough and dyspnea. While most patients benefit from conservative management and corticosteroids, some experience treatment interruptions, affecting their quality of life. The findings suggest that optimizing radiotherapy techniques and monitoring dosimetric constraints are critical for minimizing pulmonary complications and enhancing treatment outcomes.

Declarations

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Author Contributions

K.L. Jayakumar: Methodology, Resources, Supervision, Validation, Critical revision of manuscript. Rasi.S: Conceptualization, Data curation, Formal analysis,

Investigation, Writing – original draft preparation, Writing – review & editing. All authors read and approved the final manuscript.

Availability of Data and Materials

The datasets generated and/or analysed during the current study are not publicly available due to institutional data protection policies but are available from the corresponding author on reasonable request, subject to approval by the Institutional Ethics Committee.

Conflict of Interest

The authors declare that they have no conflict of interest.

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