E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.02.85

Research Article

Patient-Reported Chemotherapy-Related Toxicities in Patients with Solid Malignancies: A Prospective Observational Study

Dr. Abhinav Kakkar[1], Dr. Ramraj Meena[2], Dr. Nisha Biwal[3*]
[1]Senior Resident, Department of Radiation Oncology, SMS Medical College, Jaipur.
[2]Senior Resident, Department of Radiation Oncology, SMS Medical College, Jaipur
[3*]Resident Doctor, Department of Pharmacology, RUHS College of Medical Science, Jaipur.
Corresponding Author: Dr. Nisha Biwal
Resident Doctor, Department of Pharmacology, RUHS College of Medical Science, Jaipur.
Received: 25.05.26, Revised: 19.06.26, Accepted: 20.07.26

ABSTRACT
Background: Chemotherapy remains a cornerstone in the management of solid malignancies but is frequently associated with treatment-related toxicities that adversely affect patients' quality of life and treatment adherence. Patient-reported outcomes provide a more comprehensive assessment of symptom burden than clinician-reported evaluations and facilitate timely identification of adverse events.
Objective: To evaluate the frequency, severity, and overall burden of patient-reported chemotherapy-related toxicities among patients with solid malignancies receiving systemic chemotherapy.
Methods: A prospective observational study was conducted in the Department of Radiation Oncology at SMS Medical College, Jaipur. Fifty adult patients with histologically confirmed solid malignancies receiving chemotherapy were enrolled. Patient-reported toxicities were assessed using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Demographic characteristics, clinical variables, chemotherapy intent, and toxicity profiles were analyzed using descriptive statistics, while associations between cancer type and common toxicities were evaluated using the Chi-square test.
Results: The majority of participants were aged 40–60 years (66.0%), and 54.0% were male. Breast cancer (32.0%) was the most common malignancy, followed by colorectal (28.0%), stomach (26.0%), and head and neck cancers (14.0%). Fatigue (88.0%) was the most frequently reported toxicity, followed by loss of appetite (78.0%), nausea (54.0%), and diarrhea (50.0%). Grade 1–2 toxicities predominated, while Grade 3 toxicities occurred in 30.0% of patients. Significant associations were observed between cancer type and the occurrence of diarrhea (p=0.014), mucositis (p=0.009), and vomiting (p=0.043).
Conclusion: Patient-reported outcomes revealed a substantial burden of chemotherapy-related toxicities, with fatigue and appetite loss being the most prevalent symptoms. Routine incorporation of patient-reported toxicity monitoring may facilitate earlier symptom recognition, improve supportive care, and optimize treatment outcomes in patients with solid malignancies.

Keywords: Chemotherapy Toxicity, Patient-Reported Outcomes, Solid Malignancies, Pro-Ctcae, Ctcae Version 5.0, Supportive Oncology.

INTRODUCTION

Cancer remains one of the leading causes of morbidity and mortality worldwide, imposing a substantial public health burden despite significant advances in prevention, diagnosis, and treatment. According to the GLOBOCAN 2020 estimates, approximately 19.3 million new cancer cases and nearly 10 million cancer-related deaths occurred globally, emphasizing the growing need for effective treatment strategies and comprehensive supportive care. In India, the incidence of cancer continues to rise owing to population growth, ageing, lifestyle modifications, and improved diagnostic capabilities, making cancer management an increasingly important healthcare priority (1,2). Systemic chemotherapy continues to play a pivotal role in the treatment of solid malignancies across curative, neoadjuvant, adjuvant, and palliative settings. Although modern chemotherapeutic regimens have significantly improved survival outcomes, they are frequently accompanied by a wide spectrum of adverse effects that negatively influence patients' physical functioning, psychological well-being, quality of life, and treatment

adherence. Common chemotherapy-related toxicities include fatigue, nausea, vomiting, diarrhea, mucositis, anorexia, constipation, and dyspnea. The severity and pattern of these toxicities vary according to tumor type, treatment regimen, patient characteristics, and underlying comorbidities. Early identification and appropriate management of these symptoms are essential for minimizing treatment interruptions, reducing hospitalizations, and improving clinical outcomes (3).

Traditionally, chemotherapy-related adverse events have been documented by healthcare professionals using standardized toxicity grading systems such as the Common Terminology Criteria for Adverse Events (CTCAE). Although clinician-reported assessments remain the cornerstone of toxicity evaluation in clinical practice and research, several studies have demonstrated that clinicians frequently underestimate the frequency, severity, and impact of subjective symptoms experienced by patients. Consequently, reliance solely on physician-reported assessments may fail to capture the true burden of treatment-related toxicities, particularly those affecting daily functioning and overall quality of life (4).

Patient-reported outcomes (PROs) have emerged as an important component of contemporary oncology practice by enabling patients to directly report symptoms without clinician interpretation. These measures provide valuable information regarding the patient's perception of treatment-related adverse events and facilitate earlier recognition of clinically significant symptoms. Routine incorporation of PROs into cancer care has been associated with improved symptom control, enhanced communication between patients and healthcare providers, greater treatment adherence, and improved health-related quality of life. Furthermore, studies have demonstrated that systematic symptom monitoring using patient-reported outcome measures may reduce emergency department visits, decrease hospital admissions, and even improve overall survival among patients receiving systemic anticancer therapy (5).

To standardize patient-reported toxicity assessment, the National Cancer Institute developed the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), a validated instrument designed to capture the frequency, severity, and interference of symptomatic adverse events directly from patients. The PRO-CTCAE complements the conventional CTCAE by providing a more patient-centered assessment of treatment toxicity and has become increasingly incorporated into clinical trials and routine oncology practice. Its use facilitates more accurate recognition of symptom burden and supports individualized supportive care interventions aimed at improving patient outcomes (6).

Despite growing international evidence supporting patient-reported toxicity monitoring, data from routine clinical practice in India remain relatively limited, particularly among patients with diverse solid malignancies receiving chemotherapy. Differences in healthcare infrastructure, patient awareness, nutritional status, socioeconomic factors, and treatment accessibility may influence both the occurrence and reporting of chemotherapy-related adverse events. Therefore, locally generated evidence is essential to understand the toxicity profile experienced by Indian patients and to guide supportive care strategies within resource-constrained settings.

The present prospective observational study was undertaken to evaluate the frequency, severity, and overall burden of patient-reported chemotherapy-related toxicities among patients with solid malignancies receiving systemic chemotherapy at a tertiary care teaching hospital. By systematically documenting patient-reported symptoms and grading their severity according to CTCAE Version 5.0, this study aims to provide clinically relevant evidence that may facilitate early toxicity recognition, improve symptom management, and promote patient-centered oncology care.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of Radiation Oncology, SMS Medical College, Jaipur, Rajasthan, India. The study was designed to evaluate the frequency, severity, and overall burden of patient-reported chemotherapy-related toxicities among patients with solid malignancies receiving systemic chemotherapy in routine clinical practice. The observational design allowed the assessment of adverse events without influencing the standard treatment protocol.

Study Population

Adult patients with histologically confirmed solid malignancies who were receiving

chemotherapy in either the inpatient or outpatient setting during the study period were screened for eligibility. A total of 50 consecutive patients fulfilling the inclusion criteria were enrolled after obtaining written informed consent.

Inclusion Criteria

- Patients aged 18 years or older.
- Histologically confirmed diagnosis of a solid malignancy.
- Receiving at least one cycle of systemic chemotherapy, irrespective of treatment intent (neoadjuvant, adjuvant, or palliative).
- Ability to understand and communicate treatment-related symptoms.
- Willingness to provide written informed consent.

Exclusion Criteria

- Patients with hematological malignancies.
- Patients receiving only radiotherapy, surgery, hormonal therapy, or targeted therapy without concurrent chemotherapy.
- Patients with severe cognitive impairment or psychiatric illness preventing reliable symptom reporting.
- Critically ill patients unable to complete the assessment.
- Patients unwilling to participate in the study.

Sample Size

The study included 50 patients who satisfied the eligibility criteria during the study period. Consecutive sampling was employed to minimize selection bias and to ensure representation of patients receiving routine chemotherapy for different solid malignancies.

Data Collection

Baseline demographic and clinical information was collected using a structured case record form. The recorded variables included age, sex, body mass index (BMI), type of malignancy, disease stage, presence of comorbidities, and treatment intent. Clinical information was obtained from patients' medical records and verified through treating oncologists whenever necessary.

Assessment of Chemotherapy-Related Toxicities

Patient-reported chemotherapy-related toxicities were evaluated using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Patients were interviewed during their chemotherapy visits and were encouraged to report all treatment-related symptoms experienced since the previous treatment cycle. Symptoms assessed included fatigue, loss of appetite, nausea, vomiting, diarrhea, mucositis, dyspnea, constipation, rash, chest pain, and other clinically relevant adverse events.

Each reported toxicity was graded according to CTCAE Version 5.0. Toxicities were categorized as Grade 1 (mild), Grade 2 (moderate), or Grade 3 (severe). For each participant, the highest severity grade reported for each adverse event was documented. The overall toxicity burden was determined by calculating the number of adverse events experienced by each patient and identifying the presence of any Grade 3 toxicity.

Outcome Measures

The primary outcome was the frequency of patient-reported chemotherapy-related toxicities.

Secondary outcomes included:

- Distribution of toxicity severity according to CTCAE Version 5.0.
- Overall burden of chemotherapy-related adverse events.
- Frequency of patients experiencing multiple toxicities.
- Association between cancer type and commonly reported chemotherapy-related toxicities.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using the Statistical Package for the Social Sciences (SPSS) software (IBM SPSS Statistics, Version 26.0; IBM Corp., Armonk, NY, USA). Continuous variables were summarized using mean ± standard deviation or median with interquartile range, depending on data distribution. Categorical variables were expressed as frequencies and percentages.

Associations between categorical variables were evaluated using the Chi-square test or Fisher's exact test wherever appropriate. A two-sided p-value of less than 0.05 was considered statistically significant. Statistical findings were presented using tables to facilitate interpretation of demographic characteristics, toxicity profiles, severity grading, and associations between cancer type and chemotherapy-related adverse events.

RESULTS

A total of 50 patients with histologically confirmed solid malignancies receiving systemic chemotherapy were included in the study. The results summarize the baseline demographic and clinical characteristics of the study population, the distribution of chemotherapy intent and nutritional status, the frequency and severity of patient-reported chemotherapy-related toxicities, and the association between cancer type and commonly reported adverse events.

Baseline Demographic and Clinical Characteristics

Table 1 presents the baseline demographic and clinical profile of the study participants. The majority of patients belonged to the 40–60-year age group (66.0%), while 18.0% were older than 60 years and 16.0% were younger than 40 years. The study population consisted of 27 (54.0%) males and 23 (46.0%) females.

Breast carcinoma was the most common malignancy, accounting for 32.0% of cases, followed by colorectal cancer (28.0%), stomach cancer (26.0%), and head and neck malignancies (14.0%). Most patients presented with Stage III disease (46.0%), whereas Stage II and Stage IV disease constituted 32.0% and 16.0% of cases, respectively. Only 6.0% of patients had Stage I disease. Comorbid illnesses were present in 38.0% of participants, while 62.0% had no documented comorbidity, indicating that the majority of patients were receiving chemotherapy without significant associated medical conditions.

Table 1. Baseline Demographic and Clinical Characteristics of the Study Participants (N = 50)

Variable	Category	n (%)
Age (years)	<40	8 (16.0)
	40–60	33 (66.0)
	>60	9 (18.0)
Sex	Male	27 (54.0)
	Female	23 (46.0)
Cancer type	Breast	16 (32.0)
	Colorectal	14 (28.0)
	Stomach	13 (26.0)
	Head & Neck	7 (14.0)
Disease stage	I	3 (6.0)
	II	16 (32.0)
	III	23 (46.0)
	IV	8 (16.0)
Comorbidity	Yes	19 (38.0)
	No	31 (62.0)

Chemotherapy Intent and Body Mass Index

The distribution of chemotherapy intent and BMI categories is summarized in Table 2. Adjuvant chemotherapy was administered to 44.0% of patients, while 42.0% received neoadjuvant chemotherapy. Palliative chemotherapy accounted for 14.0% of treatment indications. Regarding nutritional status, more than half of the participants (56.0%) were overweight or obese, whereas 40.0% had a normal BMI and only 4.0% were underweight. These findings indicate that curative-intent chemotherapy predominated in the study cohort and that overweight or obesity was relatively common among the participants.

Table 2. Distribution of Chemotherapy Intent and BMI (N = 50)

Variable	Category	n (%)
Chemotherapy intent	Adjuvant	22 (44.0)
	Neoadjuvant	21 (42.0)
	Palliative	7 (14.0)
BMI category	Underweight	2 (4.0)
	Normal	20 (40.0)
	Overweight/Obese	28 (56.0)

Frequency of Patient-Reported Chemotherapy Toxicities

The frequency of patient-reported chemotherapy-related toxicities is shown in Table 3. Every patient (100.0%) experienced at least one chemotherapy-related adverse event during the study period. Fatigue was the most frequently reported symptom, affecting 88.0% of patients, followed by loss of appetite (78.0%), nausea (54.0%), diarrhea (50.0%), and mucositis (40.0%). Vomiting was reported by 32.0% of participants, while dyspnea and constipation occurred in 28.0% and 22.0%, respectively. Rash (6.0%) and chest pain (4.0%) were relatively uncommon. Overall, constitutional and gastrointestinal toxicities represented the predominant symptom burden among patients receiving chemotherapy.

Table 3. Frequency of Patient-Reported Chemotherapy Toxicities (N = 50)

Side Effect	n (%)
Fatigue	44 (88.0)
Loss of appetite	39 (78.0)
Nausea	27 (54.0)
Diarrhea	25 (50.0)
Mucositis	20 (40.0)
Vomiting	16 (32.0)
Dyspnea	14 (28.0)
Constipation	11 (22.0)
Rash	3 (6.0)
Chest pain	2 (4.0)
At least one side effect	50 (100.0)

Severity and Overall Burden of Chemotherapy-Related Toxicities

Table 4 summarizes the maximum severity grade of patient-reported toxicities according to CTCAE Version 5.0 along with the overall toxicity burden. Grade 1 and Grade 2 toxicities predominated across nearly all adverse events. Fatigue was the most common moderate toxicity, with 44.0% of patients reporting Grade 2 symptoms. Grade 3 toxicities were relatively infrequent and were observed mainly in fatigue (4.0%), loss of appetite (6.0%), diarrhea (4.0%), nausea (4.0%), mucositis (4.0%), dyspnea (2.0%), and chest pain (2.0%). No Grade 3 vomiting, constipation, or rash was reported.

Overall, all participants experienced at least one chemotherapy-related toxicity. Most patients (84.0%) reported fewer than six adverse events, whereas 16.0% experienced six or more toxicities. Grade 3 toxicity of any type was documented in 30.0% of patients, while the remaining 70.0% experienced only Grade 1 or Grade 2 adverse events. These findings suggest that although chemotherapy-related toxicities were universally reported, the majority were mild to moderate in severity.

Table 4. Severity and Overall Burden of Chemotherapy-Related Toxicities (N = 50)

Variable	n (%)
Patients with ≥1 side effect	50 (100.0)
Patients with <6 side effects	42 (84.0)
Patients with ≥6 side effects	8 (16.0)
Patients with any Grade 3 toxicity	15 (30.0)
Patients with Grade 1–2 toxicities only	35 (70.0)

Association Between Cancer Type and Common Chemotherapy Toxicities

The relationship between cancer type and commonly reported toxicities is presented in Table 5. Fatigue and loss of appetite were highly prevalent across all malignancies without statistically significant differences (p=0.612 and p=0.728, respectively). However, significant associations were observed for diarrhea (p=0.014), mucositis (p=0.009), and vomiting (p=0.043). Diarrhea occurred most frequently among patients with colorectal cancer, whereas mucositis was particularly common in patients with head and neck malignancies. Vomiting was reported more frequently among patients with stomach cancer than in other cancer groups. Nausea showed no statistically significant variation according to cancer type (p=0.381).

Table 5. Association Between Cancer Type and Common Patient-Reported Toxicities

Toxicity	P value
Fatigue	0.612
Loss of appetite	0.728
Diarrhea	**0.014**
Mucositis	**0.009**
Nausea	0.381
Vomiting	**0.043**

The observed findings indicate that while constitutional symptoms such as fatigue and anorexia were consistently reported across different malignancies, gastrointestinal toxicities and mucosal complications varied significantly according to cancer type, highlighting the importance of individualized supportive care during chemotherapy.

DISCUSSION

The present prospective observational study evaluated patient-reported chemotherapy-related toxicities among patients with solid malignancies receiving systemic chemotherapy in a tertiary care center. The findings demonstrated that every participant experienced at least one treatment-related adverse event, with fatigue, loss of appetite, nausea, diarrhea, and mucositis being the most frequently reported symptoms. Although chemotherapy-related toxicities were universal, most were of mild to moderate severity, while severe (Grade 3) toxicities were observed in less than one-third of patients. These findings highlight the considerable symptom burden experienced during chemotherapy and emphasize the importance of incorporating patient-reported outcomes into routine oncology practice for timely symptom recognition and management.

Fatigue emerged as the most common chemotherapy-related toxicity, affecting 88% of patients, followed by loss of appetite in 78%. These observations are consistent with the national survey conducted by **Henry et al.**, who reported that fatigue remains one of the most distressing symptoms experienced by patients undergoing cancer treatment and substantially affects daily activities, physical functioning, and overall quality of life (7). Similarly, anorexia and reduced nutritional intake have been recognized as frequent consequences of systemic chemotherapy, contributing to weight loss, reduced treatment tolerance, and diminished functional status. The high prevalence of these constitutional symptoms observed in the present study reinforces the need for routine symptom assessment and multidisciplinary supportive care, including nutritional counseling, rehabilitation, and early symptom-directed interventions.

Gastrointestinal toxicities constituted another major component of the symptom burden. More than half of the patients experienced nausea, while diarrhea affected half of the study population. Vomiting and mucositis were also commonly reported. These findings are comparable to those reported by **Galizia et al.**, who demonstrated that gastrointestinal adverse events frequently persist throughout chemotherapy and may continue even after treatment completion, negatively influencing patients' quality of life and treatment compliance (8). The occurrence of gastrointestinal symptoms may vary depending on chemotherapy regimen, cancer type, and individual patient characteristics; nevertheless, proactive supportive measures such as antiemetic prophylaxis, hydration, nutritional optimization, and early management of diarrhea and mucosal toxicity remain essential components of comprehensive cancer care.

The present study further demonstrated that Grade 1 and Grade 2 toxicities predominated across almost all adverse events, whereas Grade 3 toxicities occurred in only 30% of patients. These findings indicate that although chemotherapy-related symptoms are highly prevalent, severe toxicities are relatively less common when patients receive standard supportive care. The grading of adverse events according to the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 enabled standardized evaluation of symptom severity and facilitated objective comparison across different toxicities (9). Standardized toxicity grading is particularly important for identifying patients requiring treatment modification, hospitalization, or intensive supportive interventions.

An important finding of this study was the significant association between cancer type and specific chemotherapy-related toxicities. Diarrhea occurred more frequently among patients with colorectal malignancies, whereas mucositis was particularly common in head and neck cancers. Vomiting was more frequently

observed among patients with gastric malignancies. These differences are biologically plausible because chemotherapy regimens differ according to tumor site, resulting in distinct toxicity profiles. Recognition of cancer-specific adverse event patterns allows clinicians to anticipate complications, individualize supportive care strategies, and improve treatment tolerability. Conversely, fatigue and appetite loss occurred uniformly across all cancer types, suggesting that these symptoms represent generalized systemic effects of chemotherapy irrespective of the primary malignancy.

The findings of the present study support the growing emphasis on patient-reported outcome measures as an integral component of oncology practice. Patient-reported symptoms frequently provide information that may not be completely captured during routine clinician assessments, thereby facilitating earlier identification of clinically significant adverse events and improving communication between patients and healthcare providers. Incorporation of structured patient-reported toxicity monitoring into routine clinical practice may therefore contribute to improved symptom control, enhanced treatment adherence, and better patient-centered care.

Certain limitations should be acknowledged while interpreting the present findings. The study was conducted at a single tertiary care institution with a relatively small sample size, which may limit the generalizability of the results. In addition, patients with different malignancies and chemotherapy regimens were analyzed together, introducing heterogeneity in toxicity profiles. The observational design also precluded assessment of causal relationships or long-term changes in symptom burden. As discussed by **Rothwell**, findings from single-center observational studies should be interpreted cautiously when extrapolating to broader patient populations (10). Future multicenter studies with larger sample sizes, longer follow-up, and disease-specific analyses are warranted to validate these observations and further establish the role of patient-reported toxicity monitoring in routine oncology practice.

CONCLUSION

Chemotherapy-related toxicities are common among patients with solid malignancies, with fatigue, loss of appetite, nausea, diarrhea, and mucositis representing the most frequently reported symptoms. Although most adverse events were mild to moderate in severity, a substantial proportion of patients experienced severe toxicities requiring close clinical attention. Significant variations in gastrointestinal and mucosal toxicities according to cancer type further emphasize the need for individualized supportive care.

Routine implementation of standardized patient-reported toxicity assessment alongside conventional clinical evaluation can improve early symptom recognition, optimize supportive care, enhance treatment adherence, and promote patient-centered oncology practice. Larger multicenter studies are recommended to further validate these findings and strengthen the integration of patient-reported outcomes into routine cancer care.

REFERENCE

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*. 2021;71(3):209-49.
2. Mathur P, Sathishkumar K, Chaturvedi M, Das P, Sudarshan KL, Santhappan S, et al. Cancer statistics, 2020: Report from National Cancer Registry Programme, India. *JCO Glob Oncol*. 2020;6:1063-75.
3. Pearce A, Haas M, Viney R, Pearson SA, Haywood P, Brown C, et al. Incidence and severity of self-reported chemotherapy side effects in routine care: A prospective cohort study. *PLoS One*. 2017;12(10):e0184360.
4. Di Maio M, Gallo C, Leighl NB, Piccirillo MC, Daniele G, Nuzzo F, et al. Symptomatic toxicities experienced during anticancer treatment: Agreement between patient and physician reporting in three randomized trials. *J Clin Oncol*. 2015;33(8):910-5.
5. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. *J Clin Oncol*. 2016;34(6):557-65.
6. Basch E, Reeve BB, Mitchell SA, Clauser SB, Minasian LM, Dueck AC, et al. Development of the National Cancer Institute Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). *J Natl Cancer Inst*. 2014;106(9):dju244.

7. Henry DH, Viswanathan HN, Elkin EP, Traina S, Wade S, Cella D. Symptoms and treatment burden associated with cancer treatment: Results from a cross-sectional national survey in the United States. *Support Care Cancer.* 2008;16(7):791-801.
8. Galizia D, Milani A, Geuna E, Martinello R, Cagnazzo C, Foresto M, et al. Self-evaluation of duration of adjuvant chemotherapy side effects in breast cancer patients: A prospective study. *Cancer Med.* 2018;7(9):4339-44.
9. National Cancer Institute. *Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0*. Bethesda (MD): National Cancer Institute; 2017.
10. Rothwell PM. External validity of randomised controlled trials: "To whom do the results of this trial apply?". *Lancet*. 2005;365(9453):82-93.