Original Article

Evaluation of Chemotherapy-Induced Toxicities and Quality of Life Using FACT-G7 in Cancer Patients

Siddharth Arora[1], Sulagna Mohanty[2], Kriti Grover[3]

[1]Assistant Professor, Radiation Oncology, Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh, India, [2]Assistant Professor, Radiation Oncology, AHPGIC, Cuttack, India, [3]Assistant Professor, General Pathology, Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh, India,

Abstract

Background: Chemotherapy remains an essential modality in cancer treatment but is frequently associated with adverse drug reactions (ADRs) that can affect treatment adherence and quality of life. Head and neck cancers (HNCs) constitute a major cancer burden in India, where platinum- and taxane-based regimens are commonly used. Monitoring the pattern and impact of ADRs is crucial for optimizing therapy and ensuring patient safety. The objective is to evaluate the patterns, severity, causality, and preventability of chemotherapy-induced ADRs among cancer patients in a tertiary care center and to assess their impact on quality of life. **Material and Methods:** A prospective, observational study was conducted over six months among 221 cancer patients receiving chemotherapy, with or without concurrent radiotherapy or surgery. Data were collected on patient demographics, treatment regimens, and ADR profiles. Causality, severity, and preventability were assessed using the Naranjo Probability Scale, Hartwig and Siegel Severity Scale, and Modified Schumock and Thornton Criteria, respectively. Quality of life was evaluated using the Functional Assessment of Cancer Therapy–General (FACT-G7) questionnaire. **Results:** The most affected age group was 41–50 years (33.9%), with a male predominance (59.7%). Head and neck cancers were most common (42.5%), particularly buccal mucosa (21.7%) and tongue (10.9%) cancers, followed by breast carcinoma (17.1%). The most frequently reported ADRs were nausea and vomiting (50.2%), fatigue (45.7%), onycholysis (33.9%), decreased appetite (31.2%), and anemia (27.1%). Cisplatin was the drug most commonly associated with ADRs (52.1%), followed by paclitaxel + carboplatin (14.0%). According to the Hartwig scale, 64.7% of ADRs were mild, 29.8% moderate, and 5.4% severe. The Naranjo scale classified most as possible (64.2%) and probable (27.1%). Based on the Schumock and Thornton criteria, 57.8% were not preventable, 24.3% probably avoidable, and 17.9% definitely avoidable. **Conclusion:** ADRs are common among cancer patients receiving chemotherapy, though most are mild to moderate and manageable. Cisplatin-based regimens are the leading cause of ADRs. Strengthening pharmacovigilance systems and conducting regular quality-of-life assessments can help detect, prevent, and manage ADRs early, thereby improving patient outcomes and therapeutic safety.

Keywords: Adverse drug reaction, Chemotherapy, Cisplatin, Pharmacovigilance, Cancer, Quality of life, Head, and neck cancer.

Received: 05 December 2025 **Revised: 25 December 2025** **Accepted: 02 January 2026** **Published: 08 January 2026**

Introduction

Cancer incidence in India is a major public health concern, with the country ranking second in Asia and third globally. The lifetime risk of cancer is 11.0% and is rising. The most common cancers are oral cavity and lung cancers in men, and cervical and breast cancers in women, together accounting for over 50% of cancer-related deaths. Chemotherapy plays a key role in cancer management as a primary, adjuvant, or palliative treatment. The selection of neoadjuvant chemotherapy regimens is guided by multiple factors, such as the patient's performance status, renal function (typically assessed using the Cockcroft–Gault formula to estimate creatinine clearance), financial resources, and individual preferences. Concurrent chemoradiotherapy (CCRT) has demonstrated benefits in improving locoregional control, overall survival, and the potential for organ preservation. Additionally, when chemotherapy is administered as part of CCRT, it may also exert systemic effects, thereby helping to reduce the risk of distant metastases. However, it is commonly associated with adverse drug reactions, which can affect treatment adherence and quality of life. An adverse drug reaction (ADR) refers to an undesirable or harmful response to a medication. ADRs are responsible for a significant share of the rising healthcare costs and human suffering.[1] The World Health Organization defines an adverse drug reaction as a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.[2] Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects.[3] Adverse drug reactions (ADRs) can significantly worsen a patient's suffering by delaying recovery and, in some cases, leading to hospitalization.

Address for correspondence: Dr. Siddharth Arora, Assistant Professor, Radiation Oncology, Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh, India.
E-mail: drsiddhartharora25@gmail.com

DOI:
10.21276/amit.2026.v13.i1.289

How to cite this article: Arora S, Mohanty S, Grover K. Evaluation of Chemotherapy-Induced Toxicities and Quality of Life Using FACT-G7 in Cancer Patients. Acta Med Int. 2026;13(1):21-26.

In response to the growing need for drug safety monitoring, the Pharmacovigilance Program of India (PvPI) was established in 2010. Its goal is to monitor drug safety and develop a comprehensive ADR database for the Indian population.

Despite such initiatives, one of the major challenges to ensuring drug safety in India is the lack of a well-structured and efficient ADR monitoring and reporting system. Among the drugs associated with the highest incidence of ADRs are antineoplastic agents, as identified by a study conducted in Southern India.[4] Furthermore, a recent global analysis spanning 10 years indicated that high-income countries report more ADRs associated with immunomodulating and antitumor drugs, possibly reflecting more robust surveillance systems or differing usage patterns.[5,6] This study aims to assess adverse drug reactions occurring with or without concurrent chemotherapy in a defined patient population.

Materials and Methods

A single-center, prospective observational study was conducted over 6 months, from March 2025 to August 2025, to determine the pattern of ADRs in cancer patients. The study included patients over the age of 18 who had received at least three cycles of chemotherapy, and those who had undergone radiotherapy or surgery (pre- or post-operative). Cancer subsites included the majority in the head and neck and thoracic regions, including breast, lung, and esophagus. Patients over 80 years of age, pregnant women, and those unwilling to participate were excluded. Data collection involved the following: Patient demographics (Age, sex, diagnosis); clinical and treatment information (Suspected drugs, dosage, frequency); ADR details (Event description, affected system, type and severity of ADR, outcome, and medications used for ADR management).

Assessment Tools:

Naranjo Probability Scale:

1. This tool assesses the likelihood of whether an ADR is actually due to the drug rather than the result of other factors. It consists of 10 questions, scored as follows >9- Definite;5–8: Probable;1–4: Possible.[7]
2. Hartwig Severity Scale: ADRs are categorized using this scale as mild (Levels 1-2), moderate (Levels 3–5), and severe (Levels 6-7).[8]
3. Modified Schumock and Thornton Criteria: This tool was used to assess the preventability of ADRs.

Quality of Life Assessment: The Functional Assessment of Cancer Therapy – General – 7 Item Version (FACT-G7) was used to evaluate patients' quality of life. This validated tool focuses on key concerns relevant to cancer patients, offering a concise yet comprehensive assessment. It encompasses the subsequent subscale domains: physical, social/family, emotional, and functional well-being. FACT-G7 is well-suited for rapid quality of life assessment in clinical and research settings, particularly for patients undergoing chemotherapy or radiation therapy.

Results

A total of 221 patients were enrolled in the study over six months. The most commonly affected age group was 41–50 years, accounting for 33.9% of patients, followed closely by those aged 50 years or older (32.5%) [Table 1]. These age groups also reported the highest number of adverse drug reactions (ADRs). The study showed a male predominance, with 59.7% male patients compared to 40.3% female patients, indicating that males are 1.48 times more affected than females.

Regarding treatment modalities, 52% of patients received concurrent chemoradiotherapy, while the remaining 48% received chemotherapy alone [Figure 1].

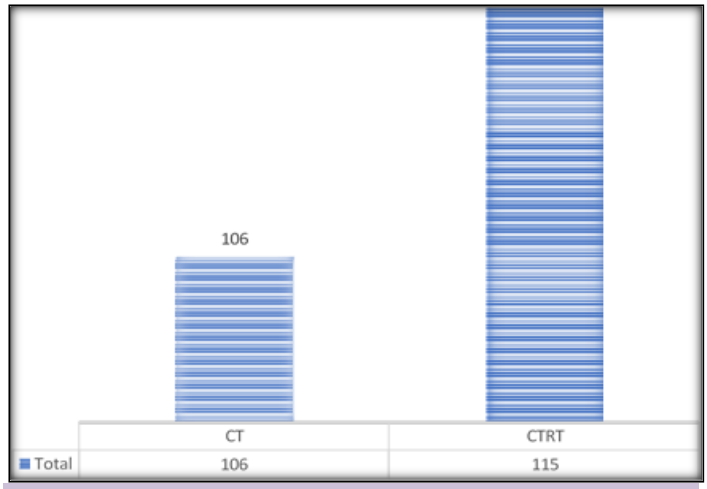


Figure 1: Distribution of cases based on treatment modalities; CT (Chemotherapy), CTRT (Chemoradiotherapy)

Table 1: Age distribution of study participants

Age group	No. of patients	Percentage
0-20	2	0.9%
21-30	14	6.3%
31-40	35	15.8%
41-50	75	33.9%
51-60	72	32.5%
>60	23	10.4%

Among these, postoperative head and neck cancer cases were the most common, accounting for 42.5% of the cases. Within this group, carcinoma of the buccal mucosa (21.7%) and carcinoma of the tongue (10.9%) were particularly frequent.

Other commonly observed cancer types included carcinoma of the breast (17.1%), oropharynx (10.9%), larynx (7.2%), cervix (4.97%),
and gall bladder (4.07%) [Table 2].

Table 2: Distribution of cancer types and subsites among patients (n = 221).

Cancer	No. of patients	Percentage
Post-operative head and neck		
Subsite		
Tongue	24	10.85%
Alveolus	14	6.3%
Buccal Mucosa	48	21.7%
Retromolar trigone	6	2.7%
Lips	1	0.9%
Metastatic head and neck	1	0.9%
Subsite		
Oropharynx	24	10.85%
Larynx	16	7.2%
Nasopharynx	2	0.9%
Lung	5	2.26%
Ovary	6	2.71%
Esophagus	7	3.16%
Cervix	11	4.97%
Vault	2	0.9%
Breast Carcinoma	38	17.1%
Gall bladder	9	4.07%
Brain	2	0.9%
Prostate	2	0.9%
Colon	1	0.45%
Others	2	0.9%

The most commonly used chemotherapeutic regimen was a combination of cisplatin and 5-fluorouracil (5-FU), responsible for 46.2% of the ADRs. This was followed by the paclitaxel and carboplatin regimen (38.6%), and then by docetaxel combined with cisplatin and 5-FU (10.3%). Regimens with cisplatin and 5-FU alone and paclitaxel alone each accounted for 2.3% of ADRs. The most frequently reported ADRs were nausea and vomiting (50.2%), fatigue (45.7%), onycholysis (33.9%), anemia (27.1%), alopecia (24.4%), and constipation (22.1%). Other notable ADRs included appetite loss (31.1%), mucositis (19%), electrolyte disturbances (16.7%), myelosuppression (9%), ototoxicity (6.7%), thrombocytopenia (4.1%), and hiccups (1.6%) [Table 3].

Table 3: Distribution of various adverse drug reactions (ADRs) among patients (n = 221). ADRs:

Types of ADRs	No. of patients	Percentage
Anemia	60	27.14%
Mucositis	42	19.05%
Electrolyte Disturbances	37	16.7%
Nause and vomiting	111	50.2%
Nephrotoxicity	4	1.8%
Neurotoxicity	0	0%
Ototoxic effects	15	6.7%
Sensitivity reactions	1	0.45%
Alopecia	54	24.45
Neutropenia	9	4.07%
Myelosuppression	20	9.04%
Hiccups	39	17.6%
Transient elevation of LFTs	5	2.26%
Decreased Appetite	69	31.25%
Cardiac Effects	0	0%
Fatigue	101	45.7%
Pneumonia	6	2.7%
Diarrhea	13	5.8%
Constipation	49	22.1%
Onycholysis	75	33.9%

Adverse drug reactions; LFTs: liver function tests

The gastrointestinal system was most affected by ADRs, accounting for 45.1% of cases, followed by the integumentary system (27.7%). The hematological system was affected in 23.1% of the patients. The renal system was involved in only 1.8%, and the central nervous and cardiac systems were the least affected [Table 4].

Table 4: Distribution of systems affected

System affected	Percentage
Gastrointestinal	45.1%
Integumentary	27.7%

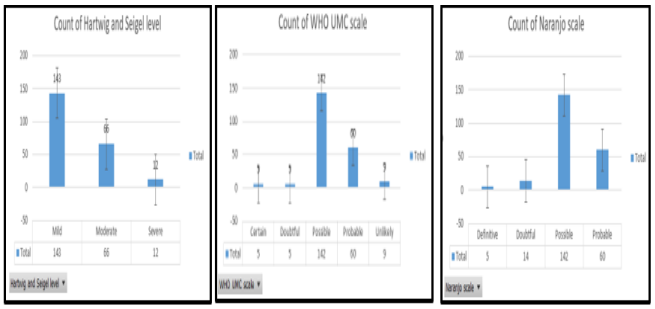
Hematological	23.1%
Renal	1.8%
Central nervous system	1.2%
Cardiac	1.1%

Among single-agent chemotherapy drugs, cisplatin was the most frequently used (52.1%), followed by paclitaxel (3.61%), trastuzumab (3.61%), docetaxel (0.9%), and temozolomide (0.9%). Among double-drug regimens, paclitaxel with carboplatin (14.02%) was the most used, followed by epirubicin with cyclophosphamide (7.2%) and gemcitabine with cisplatin (3.16%) [Table 5].

Table 5: Drugs Associated with Adverse Drug Reactions (ADRs) among Study Patients (n = 221)

Drugs Causing ADRs	No. of Patients	Percentage
Cisplatin	116	52.1%
Paclitaxel + Carboplatin	31	14.02%
Epirubicin +Cyclophosphamide	16	7.2%
Gemcitabine +Cisplatin	7	3.16%
Gemcitabine +Carboplatin	7	3.16%
Gemcitabine +Oxaliplatin	2	0.90%
Docetaxel +Cyclophosphamide	4	1.8%
Docetaxel +Cyclophosphamide + 5Fluorouracil	12	5.42%
Paclitaxel	8	3.61%
Temozolamide	2	0.90%
Trastuzumab	8	3.61%
Paclitaxel+ Trastuzumab	4	1.8%
Docetaxel	2	0.90%
Others	2	0.90%

Assessment of ADR severity using the modified Hartwig and Siegel scale showed that 64.7% were mild, 29.8% were moderate, and 5.4% were severe. According to the WHO–UMC causality assessment scale, most ADRs were classified as possible (64.2%), followed by probable (27.1%), and doubtful (6.3%). Evaluation of preventability using the modified Schumock and Thornton scale indicated that 57.83% of ADRs were not preventable, 24.3% were probably preventable, and 17.86% were definitely preventable.



2a 2b 2c

Figure 2: Assessment tools: 2a: modified Hartwig and Siegel scale; 2b: WHO–UMC causality assessment scale; 2c: modified Schumock and Thornton scale.

The Functional Assessment of Cancer Therapy–General 7-item scale (FACT-G7) was used to assess participants' overall quality of life (QoL) by examining key domains such as physical well-being, emotional well-being, social and family support, and functional capacity.

Analysis of the data revealed a consistent pattern of improvement from the first to the second visit among both male and female participants. For males, the mean QoL score increased from

72.10 ± 20.23 during the initial assessment to 75.50 ± 22.31 at follow-up, indicating a modest yet meaningful enhancement in perceived well-being. Similarly, females demonstrated an increase from 74.50 ± 18.31 to 77.50 ± 24.31, reflecting slightly higher overall QoL scores compared to their male counterparts at both time points [Table 6]. The improvements observed across visits may suggest beneficial effects of ongoing treatment, better symptom control, or increasing psychological adaptation as patients progressed through their care journey. Additionally, the relatively large standard deviations in both groups highlight considerable variability in individual experiences, which is common in heterogeneous cancer populations with differing disease burdens and treatment responses. Overall, the upward trend in QoL underscores the importance of continuous monitoring and supportive interventions tailored to patient needs throughout the course of treatment.

Table 6: Functional Assessment of Cancer Therapy – General – 7 Item Version (FACT-G7)

Domain	Total Subdomain	Score	
Physical well being	7	0-4	
Emotional Well being	6	0-4	
Social/Family well being	7	0-4	
Functional well being	7	0-4	
Mean		1st visit	2nd visits
QoL in males	Mean ± SD	72.10±20.23	75.5±22.31
Qol in females	Mean ± SD	74.5±18.31	77.5±24.31

[Table 6]: Quality of life (Qol) scores measured using the Functional Assessment of Cancer Therapy–General 7-item scale (FACT-G7) at the first and second visits among male and female participants. The table presents mean ± standard deviation (SD) values for each group, demonstrating an overall improvement in quality-of-life scores over time. Females showed slightly higher mean scores across both visits compared to males, although both groups exhibited a similar upward trend.

Discussion

Cancer is a multicellular disease that can arise from virtually any cell type or organ system in the body.[9] It has become a global health burden and is now one of the leading causes of mortality in developing countries, driven by rapid globalization, unhealthy lifestyles, and increased adoption of Western dietary patterns, which have contributed to the growing incidence of cancer in these regions.[10] In India, cancer incidence continues to rise. Currently, around 2.5 million individuals are living with cancer. Each year, more than 700,000 new cancer cases are registered, with an annual mortality of approximately 556,400. Chemotherapy is still a mainstay of oncological care among the many current treatment options. Although highly effective, chemotherapeutic agents are known for their narrow therapeutic window and significant toxicity. The spectrum of adverse drug reactions (ADRs) associated with these agents has broadened, often leading to reduced quality of life, interruption of therapy, and loss of productivity for patients.[7,11] Despite their clinical importance, studies focusing on the pattern of ADRs in Indian cancer patients are scarce. Hence, this study was designed to evaluate the safety profile of anticancer drugs and generate baseline data by assessing ADRs in patients receiving chemotherapy at a tertiary care teaching hospital in Gujarat, India. This was a cross-sectional, observational study conducted over 6 months in the oncology department. A total of 683 ADR reports were collected from 198 patients who met the study's inclusion and exclusion criteria. Among the enrolled patients, 64.14% were female, and 35.85% were male. This aligns with findings from previous studies by Rout A et al., Sowmya MS et al., and Behera et al,[12] which reported a higher ADR incidence in females. A UK review by Martin et al. across 48 cohort studies also confirmed this trend, attributing it to higher healthcare-seeking behavior among women. In contrast, studies by Sunil Bellare et al. and Prasad et al,[13,14] found that ADRs were more common in males. This variability may be due to pharmacokinetic and pharmacodynamic differences, influenced by hormonal variations in females that can affect drug metabolism and response. Causality assessment was performed using the Naranjo Probability Scale. The results showed: Possible ADRs 49.34%, Probable ADRs 47.58%, doubtful ADRs 3.07%, and definite ADRs 0% (due to the absence of drug re-challenge). These findings are consistent with studies by Chopra et al. and Swathi et al,[15] which found that most ADRs fell into the "possible" or "probable" categories. However, the Sharma et al. study population had a greater proportion of "probable" adverse drug reactions. Similar studies can be used to identify iatrogenic adverse effects and may help in preventing such occurrences in the future. The modified Hartwig and Siegel scale was used to assess ADR severity. Clearly, 91.21% of all adverse drug reactions (ADRs) were mild in severity. Only 0.73% of ADRs were severe, as seen in the present study. These results mirror those of Chopra et al.[15] However, other studies, such as those by Sharma et al. and Swathi et al., reported a higher proportion of moderate ADRs. We used the modified Schumock and Thornton criterion to evaluate preventability. The distribution was as follows: not preventable 57.83%, probably preventable 24.3% and definitely preventable as17.86%. These results are consistent with those of Rout et al. and Sharma et al., whereas Swathi et al. reported a greater number of definitely preventable ADRs. In addition to the overall improvement in quality-of-life scores across visits, the comparison between males and females highlights subtle yet meaningful differences in patient-reported outcomes. Females consistently reported higher baseline and follow-up scores, which may reflect variations in coping strategies, social support networks, or perceptions of well-being between genders. The steady increase observed in both groups suggests that patients may be adapting positively to their treatment pathways, benefiting from supportive care measures, or experiencing relief from initial symptoms as therapy progresses. These findings emphasize the value of routine QoL assessments with concise tools such as the FACT-G7, which provide important insights into patient experiences that may not be captured by clinical outcomes alone. Continuous monitoring enables healthcare providers to identify individuals who may require additional support and tailor interventions to enhance overall well-being throughout the treatment trajectory. This study emphasizes the need for structured ADR monitoring in cancer care settings. With a majority of reactions being mild to moderate, possibly preventable, and linked to gender and treatment regimen, findings reinforce the importance of pharmacovigilance and individualized treatment planning. Regular assessment of ADR patterns can help optimize therapy and improve patient outcomes.

Conclusion

This study provides a comprehensive evaluation of adverse drug reactions (ADRs) and quality of life (QoL) in cancer patients receiving chemotherapy and chemoradiotherapy at a tertiary care center. The findings indicate that while a majority of ADRs were mild to moderate in severity, a notable proportion were potentially preventable, highlighting the critical role of structured pharmacovigilance in oncology practice. The gastrointestinal, hematological, and integumentary systems were most commonly affected, with cisplatin-based regimens as the predominant cause of ADRs. Assessment of QoL using the FACT-G7 scale demonstrated a gradual improvement over the course of treatment in both male and female patients, suggesting positive adaptation and the potential benefits of supportive care interventions. Gender differences in QoL scores further underscore the need for individualized patient management. Overall, the study emphasizes the importance of continuous ADR monitoring, combined with systematic QoL assessment, to optimize therapeutic outcomes, enhance patient safety, and improve the well-being of cancer patients. Implementing such patient-centered strategies can guide clinicians in tailoring treatment regimens, minimizing toxicity, and promoting better clinical and psychosocial outcomes.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Poddar S, Sultana R, Sultana R, Akbor MM, Azad MA, Hasnat A. Pattern of adverse drug reactions due to cancer chemotherapy in tertiary care teaching hospital in Bangladesh. Dhaka Univ J Pharm Sci. 2009; 8:11–6.
2. World Health Organization. International Drug Monitoring: The Role of the Hospital. Geneva: World Health Organization; 1996. Technical Report Series: No. 425.
3. Adithan C. National pharmacovigilance programme. Indian J Pharmacol. 2005; 37:347.
4. Sriram S, Ghasemi A, Ramasamy R, Devi M, Balasubramanian R, Ravi TK, et al. Prevalence of adverse drug reactions at a private tertiary care hospital in south India. J Res Med Sci. 2011; 16:16–25
5. Aagaard L and Hansen E: Side effects of antineoplastic and immunomodulating medications reported by European consumers. J Res Pharm Pract 2013; 2(1): 44.
6. Aagaard L, Strandell J, Melskens L, Petersen PS, Holme Hansen E. Global patterns of adverse drug reactions over a decade: Analyses of spontaneous reports to VigiBase™. Drug Saf. 2012; 35:1171–82. doi: 10.1007/BF03262002.
7. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981; 30:239–45. doi: 10.1038/clpt.1981.154
8. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm. 1992; 49:2229–32.
9. Soldin OP, Chung SH and Mattison DR: Sex differences in drug disposition. J Biomed Biotechnol. 2011; 2011: 7-9.
10. Gandhi M, Aweeka F, Greenblatt RM, Blaschke TF. Sex Differences in Pharmacokinetics and Pharmacodynamics. Annu Rev Pharmacol Toxicol. 2004; 44(February): 499- 523.
11. Lau PM, Stewart K, Dooley M. The ten most common adverse drug reactions (ADRs) in oncology patients: Do they matter to you? Support Care Cancer. 2004; 12:626–33. doi: 10.1007/s00520-004-0622-5.
12. Behera SK, Kishtapati CR, Gunaseelan V, Dubashi B and Chandrasekaran A: Chemotherapy Induced Adverse Drug Reactions in Cancer Patients in a Tertiary Care Hospital
13. Bellare PS, Ashwin K, Pu SP, Vinaykumar S and Kb R: A Retrospective Evaluation of Adverse Drug Reactions Due to Cancer Chemotherapy in a Tertiary Care Hospital in South India. J Young Pharm. 2016; 8(3): 251–4.
14. Prasad A, Datta PP, Bhattacharya J, Pattanayak C and Chauhan AS: Pattern of Adverse Drug Reactions Due to Cancer Chemotherapy in a Tertiary Care Teaching Hospital in Eastern India. J Pharmacovigil 2013; 1(2): 107.
15. Chopra D, Rehan HS, Sharma V and Mishra R: Chemotherapy-induced adverse drug reactions in oncology patients: A prospective observational survey. Indian J Med Paediatr Oncol 2016; 37(1): 42–6.