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ORIGINAL ARTICLE

Adverse Drug Reaction Profile Among Women Aged Forty Years and Above Receiving Anticancer Therapy: A Prospective Observational Study

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Abstract

Background: Anticancer therapies often come with a spectrum of adverse drug reactions (ADRs), which can significantly impact the quality of life and treatment adherence among patients. This prospective observational study aimed to assess the ADR profile among women aged forty and above undergoing various forms of anticancer therapy. **Methods:** A cohort of women aged forty and above, receiving anticancer therapy at a tertiary care center, was followed prospectively. ADRs were recorded during each follow-up visit and graded according to established criteria. The data were analyzed to determine the prevalence and severity of ADRs among different age groups and types of anticancer therapies. **Results:** A total of 103 women were included in the study, with a mean age of 55.83 ± 8.7 years**.** The most common therapies administered were chemotherapy, antimicrobial therapy, and hormonal therapy. The overall prevalence of ADRs was 44.78%. The most frequently reported ADRs were alopecia, anorexia, and irregular mensuration, hyperglycemia and premature menopause being the specific ADR.Older age was associated with a higher risk of certain ADRs, such as weight loss, and deranged LFTs and GI disturbances. **Conclusion:** This prospective observational study highlights the significant burden of adverse drug reactions (ADRs), with an overall prevalence of 44.78%, among women over 40 receiving anticancer therapy, with alopecia, anorexia, and menstrual irregularities being most common. Age-related ADRs included weight loss, GI disturbances, and liver dysfunction. Early recognition and management of ADRs can enhance treatment adherence and patient well-being.

Key Words

Adverse Drug Reaction, Anticancer Therepy

Introduction

Adverse drug reaction refer to harmful reactions to drug under normal usage conditions[1]. Adverse Drug Reactions (ADRs) pose significant challenges in the management of patients undergoing anticancer therapy, particularly among women aged forty and above. This demographic is often underrepresented in clinical trials, leading to a gap in the comprehensive understanding of their ADR profiles. Addressing this gap is crucial for optimizing therapeutic outcomes and improving the quality of life for this population. Among females in India, the five leading contributors to cancer-related Disability-Adjusted Life Years (DALYs) are breast cancer (232.7

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per 100, 000), cervical cancer (98.6 per 100, 000), ovarian cancer (78.9 per 100, 000), lung cancer (74.1 per 100, 000), and gallbladder cancer (58.3 per 100, 000)".[2]

Women are 50%–75% more likely than men to experience an ADR. This probably occurs due to increased drug bioavailability, greater sensitivity to medications, lower body weight, lower organ sizes, higher % of body fat, lower volume of distribution as well as greater awareness in females than in males. Surely, the same applies to drug usage in oncology.[3]

Studies have highlighted that older women with cancer are at a heightened risk for specific ADRs due to age-related changes in drug metabolism, co-morbid conditions, and concurrent medications.[4] Moreover, gender-specific factors such as hormonal fluctuations, differences in body composition, and genetic variations can further modify the ADR profile in this group. For instance, research indicates that women are more susceptible to certain chemotherapy-induced toxicities, including cardiotoxicity and neuropathy, which can lead to dose modifications or discontinuation of therapy.[5]

A prospective observational study effectively captures real-world ADR data in women aged 40+ on anticancer therapy, aiding in incidence tracking and management. This supports personalized care and improved treatment strategies.

Aims & Objectives

To evaluate the incidence, pattern, and causality of adverse drug reactions among women aged forty years and above receiving anticancer therapy in a tertiary care center.

Material and Method

This 6-month prospective study (29/11/2023–31/05/2024) was conducted at GMC Jammu after IECapproval (IEC/GMCJ/2023/1635).

A total of 103 IPD and OPD patients on anticancer therapy with suspected ADRs were evaluated.

Sample Size Calculation:The minimum required sample size was calculated using the formula:

$N= Z^2.p.(1–p)/d^2$

where:

n = required sample size

Z = Z-value (standard normal deviate) for desired confidence (1.96 for 95% CI)

p = estimated proportion (prevalence, from prior studies or pilot study)

d = absolute precision (margin of error, e.g., 0.05 for 5%)

Although the calculated minimum sample size was 96, But 103 consecutive eligible patients were recruited during the 6-month study period. This reflects the total number of eligible patients who fulfilled the inclusion criteria and consented to participate within the timeframe.

Patient data on age, therapy type, dosage, duration, frequency, and ADRs were systematically recorded. The suspected ADR are classified in terms of the causality assessment scale using the **WHO-UMC scale and the NARANJO ALGORITHM scale.** As certain, probable, possible, unlikely, conditional/unclassified and unassessable/unclassified and also by using Narnjo algorithm scale.[6] Descriptivestatistics were used to analyze the data and values areexpressed in numbers and percentages.

Prevalence of ADRs (%)=Totalnumber of patientswho experienced at least one ADR / Total no. of patients studied ×100

Inclusion Criteria:

1. Women aged e ≥ 40 years.
2. Diagnosed with malignancy (solid or hematological).
3. Receiving anticancer therapy (chemotherapy, targeted therapy, hormonal therapy).
4. Willing to provide informed consent.

Exclusion Criteria:

1. Women aged <40 years
2. Pregnant or lactating women.
3. Patients with no anticancer treatment
4. Patients unwilling to participate.
5. Patients lost to follow-up before ADR assessment.

Result

The distribution of diagnoses among 103 patients shows that Ca cervix was the most common diagnosis, accounting for 20.38% of cases, followed by Ca gall bladder (18.44%) and Caoesophagus (17.47%). Other notable diagnoses include Ca breast (16.50%) and Ca oropharynx (13.59%), while rarer diagnoses like Ca lung, AML, and other cancers each constituted less than 1% (Table 1). The incidence of adverse drug reactions (ADRs) was most frequent in the 50-60 years age group, comprising 57.28% of all cases, while 17.47% occurred in patients aged 40-50 years and 25.25% in those older than 60 (Table 2).

The most commonly observed ADRs among 234 reported reactions included alopecia (17.09%), nausea (14.95%), and anemia (12.82%). Less frequent ADRs included irregular menstruation (10.68%), constipation, and weight loss (8.54% each). Serious ADRs such as neutropenia, allergic reactions, thrombocytopenia, and death were also recorded, though at lower frequencies (Table 4). Based on the WHO-UMC scale, 51.28% of

Table 1: Distribution of the Patients According To the Frequencies of Their Diagnosis. (n=103)

S.No.	Diagnosis	Frequencies	Percentage (%)
1	Ca cervix	21	20.38
2	Ca Gall Bladder	19	18.44
3	Caoesophagus	18	17.47
4	Ca Breast	17	16.50
5	Ca oropharynx	14	13.59
6	Ca ovary	8	7.76
7	Ca lung	1	0.97
8	AML	1	0.97
9	Adenocarcinoma	1	0.97
10	Chondrosarcoma of right sacrum	1	0.97
11	Capancrease	1	0.97
12	Hepatocellular ca	1	0.97
13	Anorectal ca	1	0.97
14	Ca colon	1	O.97
15	Squamous cell carcinoma	1	0.97
16	Small cell tumour	1	0.97

Note: *Some patients had multiple primary cancers; therefore, total diagnoses exceed total patients (n=107 vs n=103)*

Table 2: Incidence of Adverse Drug Reactions in Different Age Group (n=103)

Age group	Value	%
<40-50 years	18	17.47
50-60 years	59	57.28

ADRs related to anticancer drugs were classified as "probable" in causality, while the majority of ADRs from anti-microbials were also in the "probable" and "possible" categories (Table 5).

Discussion

Oncology has advanced significantly, turning many once-terminal cancers into treatable conditions.Adjuvant chemotherapy improves survival and lowers recurrence risk.

However, anticancer drugs often have a narrow therapeutic window and cause adverse effects, especially in women.[7]

The distribution of cancer diagnoses in this study highlights the predominance of cervical cancer (20.38%), gall bladder cancer (18.44%), and esophageal cancer (17.47%) among the patients. These findings are consistent with trends reported in similar studies from India, where cervical and gall bladder cancers have been prevalent due to factors like poor screening and environmental risks. For instance, a recent study by Yadhav *et al*, (2022) found cervical cancer accounting for 22% and gall bladder cancer for 16% of cases in a similar cohort. In contrast, breast cancer (16.50%) showed a slightly lower representation in our study compared to Sharma *et al* [9] which reported breast cancer as the most common diagnosis at 20%, reflecting regional and possibly genetic variability in cancer incidence. Additionally, rarer cancers like small cell tumors and squamous cell carcinoma were similarly reported at around 1% in both studies, confirming their infrequent occurrence. This comparison underscores the need for targeted screening and prevention programs tailored to region-specific cancer burdens. In Table 2, the distribution of adverse drug reactions (ADRs) shows that the highest incidence occurs in the 50–60-year age group (57.28%), followed by those over 60 years (25.25%), and lastly those below 50 (17.47%). This age-related trend of ADRs is consistent with findings from studies in India. For instance, a study by Kalaiselvan *et al*, [10] highlights a higher prevalence of ADRs among older adults, especially those over 60, due to factors such as polypharmacy, comorbidities, and decreased physiological functions Similarly, another study in geriatric patients found that ADRs tend to increase significantly with age due to changes in drug metabolism and pharmacokinetics Shamna *et al*, [11]. These findings emphasize the need for careful drug monitoring, particularly in older populations.

The drug regimens prescribed for various cancers along with ADR, as outlined in Table 3, show a strong reliance on well-established chemotherapeutic agents such as Cisplatin, Paclitaxel, and Carboplatin for cancers like cervical, esophageal, and ovarian cancers. These combinations align with standard treatments reported in literature. For example, a study by Hannah *et al*, [12] also highlighted the efficacy of Cisplatin and Paclitaxel for cervical cancer, demonstrating significant survival benefits. Similarly, a combination of Carboplatin and Paclitaxel has been widely used in ovarian cancer treatment, as corroborated by Martín *et al*, [13] who reported high response rates in advanced-stage ovarian cancer.

However, there are differences in drug regimens for certain cancers. For instance, the use of Gemcitabine for gallbladder cancer, as mentioned in this study, aligns with findings from Aloia *et al.* [14] , which emphasized

Table 3: The Diagnosis and Different Drug Regimen given for them and ADR Profile.

S.No.	Diagnosis	Drug Regimen	ADR Profile
1	Ca cervix	Cisplatin & Paclitaxel	Alopecia, nausea, irregular menstruation, constipation, death
2	Ca Gall Bladder	Gemcitabine	Nausea, heavy vaginal bleeding, diarrhea, vomiting
3	Caoesophagus	Paclitaxel & carboplatin	Alopecia, allergic reaction (HSR), Irregular menstruation, anemia, constipation thrombocytopenia
4	Ca Breast	Paclitaxel	Anorexia, irregular mensturation
5	Ca oropharynx	Cisplatin & paclitaxel	Alopecia, nausea, irregular menstruation, constipation, death
6	Ca ovary	Paclitaxel & carboplatin	Alopecia, allergic reaction (HSR), Irregular menstruation, anem
7	Ca lung	Gefatrib	HSR, nausea, severe diarrhea
8	AML	Citrabine, Dandramycin & Filgrastin	Deranged LFTs, Neutropenia
9	Adenocarcinoma	5-Flurouracil	Dizziness, Alopecia
10	Chondrosarcoma of right sacrum	Doxorubicin & Imatinib	Anorexia, hyperglycemia
11	Capancrease	Gemcitabin & 5-flurouracil	Alopecia, GI disturbances
12	Hepatocellular ca	5-FU & Gemcitabine	Alopecia, GI disturbances
13	Anorectal ca	Oxaliplatin & 5-Flurouracil	Nausea, vomiting, diarrhea,
14	Ca colon	Oxaliplatin & capacitatrmil	Nausea, vomiting, diarrhea,
15	Squamous cell carcinoma	Cisplatin, doxorubicin	Alopecia, nausea, irregular menstruation, constipation
16	Small cell tumour	Carboplatin & Etoposide	Anemia, nausea, vomiting, Anorexia

the role of Gemcitabine as part of adjuvant chemotherapy for gallbladder cancer. In contrast, for lung cancer, the choice of Gefitinib (listed as "Gefatrib") reflects the trend towards targeted therapy in patients with specific mutations, as discussed in Mok *et al*. [15] , which reported better outcomes with EGFR inhibitors like Gefitinib.

The frequency distribution of various adverse drug reactions (ADRs) in this study highlights alopecia (17.09%) and nausea (14.95%) as the most common ADRs, which aligns with patterns commonly reported in cancer chemotherapy patients. Studies such as Bayo J*et al*, [16] have noted similar results, with nausea and vomiting being frequent side effects of cytotoxic drugs, particularly in treatments involving agents like Cisplatin and Paclitaxel. Alopecia is also a well-known ADR, especially with agents like Paclitaxel and Doxorubicin, as noted by Belum *et al* [17], where hair loss was observed in about 16-20% of chemotherapy patients.

More severe reactions like anemia (12.82%), weight loss (8.54%) and neutropenia (5.55%) are also common in chemotherapy regimens that cause myelosuppression, as shown in Reddy*et al*, [18] where such blood-related ADRs were frequent due to the impact of cytotoxic agents on bone marrow. Irregular menstruation (10.68%) and heavy vaginal bleeding (4.70%) and premature menopause (0.85%) are specific to female patients, particularly in hormonal treatments for cancers like breast or cervical cancer, as supported by Johnstone *et al*, [19]

The adverse drug reaction (ADR) profile for various drug regimens in this table aligns with commonly observed toxicities in cancer therapy. Cisplatin & Paclitaxel are often linked to alopecia, nausea, and severe outcomes like death, similar to findings by Ashrafizadeh *et a*l, [20], which noted alopecia and GI disturbances as major ADRs. Gemcitabine, used in GI cancers, frequently causes nausea, vomiting, and diarrhea, as reported by Marshall *et al*, [21]. For Paclitaxel and Carboplatin, Doxorubicin, and Imatinib, ADRs such as alopecia, hypersensitivity reactions, thrombocytopenia, and hyperglycemia are well-documented, with Falandry *et al*, [22] reporting similar effects in ovarian cancer. Use of 5-Fluorouracil (5-FU), often with Oxaliplatin, typically causes nausea, vomiting, and diarrhea, consistent with Lee *et al*, [23]. Targeted therapy like Gefitinib (Gefatrib) is associated with diarrhea and allergic reactions, as found by Mok *et al*, [24].

Table 3 summarizes the drug regimen-specific ADR profiles. Cisplatin + Paclitaxel and Paclitaxel + Carboplatin regimens accounted for the majority of ADRs, including alopecia, nausea, menstrual irregularities, and

Table 4: Frequency of Distribution of Various ADRs (n=234)

S.No.	ADR	Frequencies	% (n = 234)
1	Alopecia	40	17.09
2	Nausea	35	14.95
3	Dizziness	4	1.70
4	Irregular mensuration	25	10.68
5	Heavy vaginal bleeding	11	4.70
6	Premature menopause	4	1.70
7	Constipation	20	8.54
8	Diarrhea	7	2.99
9	Anemia	30	12.82
10	Neutropenia	13	5.55
11	Allergy /HSR	6	2.56
12	Anorexia	11	4.70
13	Thrombocytopenia	4	1.70
14	Vomiting	7	2.99
15	Weight loss	20	8.54
16	Deranged LFT	3	1.28
17	Hyperglycemia	3	1.28
18	Death	1	0.42

Table 5: CasualityAssessement of Patients to drug by using the WHO-UMC scale

S.No.	Certain%	Probable%	Possible%	Unlikely%	Unassessable%
Anticancer	2.13(5)	51.28(120)	35.05(82)	0	0
Anti-microbial	0	6.4(15)	4.25(10)	0	0
others	0	0.85(2)	0	0	0

Table 6: Drug Regimen with Specific ADR Profie.

S.No.	Drug Regimen	ADR Profile
1	Cisplatin & Paclitaxel	Alopecia, nausea, irregular menstruation, constipation, death
2	Gemcitabine	Nausea, heavy vaginal bleeding, diarrhea, vomiting
3	Paclitaxel &carboplatin	Alopecia, allergic reaction (HSR), Irregular menstruation, anemia, constipation thrombocytopenia
4	Paclitaxel	Anorexia, irregular mensturation
5	Gefatrib	HSR, nausea, severe diarrhea
6	Cytrabine, Dandramycin	Deranged LFTs, neutropenia
7	5-Flurouracil	Dizziness, Alopecia
8	Doxorubicin & Imatinib	Anorexia, hyperglycemia
9	Gemcitabin & 5- flurouracil	Heavy vaginal bleeding, dizzeness
10	5-FU & Gemcitabine	Alopecia, GI disturbances
11	Oxaliplatin & 5-Flurouracil	Nausea, vomiting , diarrhea,
12	Oxaliplatin & capacitatrmil	Nausea, vomiting , diarrhea,
13	Cisplatin & doxorubicin	Alopecia, nausea, irregular menstruation, constipation
14	Carboplatin & Etoposide	Anemia, nausea, vomiting, Anorexia

myelosuppression.

Causality assessment using the WHO-UMC scale (Table 5) shows that most ADRs were "probable" (51.28%), followed by "possible" (35.05%), and a few "certain" (2.13%). These findings match those of Varallo *et al*, [25], who reported many ADRs in cancer therapy as probable due to chemotherapy's systemic effects. The low rate of "certain" ADRs also reflects the challenge in establishing direct causality, a point emphasized by Baldo *et al*, [26] in oncology pharmacovigilance. For antimicrobial drugs, 6.4% of ADRs were probable and 4.25% possible, in line with studies such as Smith *et al*, [27], where causality is often unclear due to comorbidities and infections.

Conclusion

This study found a 44.78% prevalence of ADRs in women aged 40+ on anticancer therapy, with alopecia, nausea, and anemia being most common.ADRs were

highest in the 50–60 age group, with 51.28% deemed "probable" by WHO-UMC criteria. Findings highlight the need for individualized treatment, vigilant monitoring, and early ADR management to improve outcomes.

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