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A retrospective study on incedence of adverse effects of paclitaxel in cancer patients at tertiary care hospital

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ABSTRACT

Paclitaxel is a chemotherapeutic agent widely used for the effective treatment of various types of cancer. Paclitaxel was approved by the United States Food and Drug Administration for the treatment of various cancers such as ovarian cancer, breast cancer, advanced non-small cell lungcancer and acquired immunodeficiency syndrome (AIDS) – related Kaposi's sarcoma. Now a days Paclitaxel is used both as single and combination chemotherapy. However it is generally not tolerated well as it has serious adverse drug reactions such as hyper sensitivity reactions, neuropathy, haematological toxicity, myalgia etc. To prevent the adverse drug reactions the patientmust be treated with corticosteroids, antihistamines, and H2 antagonist prior to administration of Paclitaxel. Although Paclitaxel treatment is associated with several ADRs, it is still used by oncologist to treat different types of cancer because of its high efficacy. To report the adverse effects of paclitaxel and to review the management prescribed by the physician. A Retrospective study was conducted on the adverse effects of paclitaxel in cancer patients in Apollo hospital. A total number of 100 sample size was studied and their Demographic details along with relevant subjective and objective information was collected from the patient files from medical record department (MRD). Patients were followed up until complete chemotherapycycle. Parameters collected were tabulated in MS-Excel sheet and the ADR's along with recovery status were analysed. Total 68 ADRs were reported and 32 were not reported in which 95 were female and 5 were male where age between 51-60 are mostly effected with cancer as per our study and 260 mg of paclitaxel was most commonly used. Patients showed shortness of breath followed by nausea and vomiting majorly. 68% ADRs were reported on administration of paclitaxel drug, where vomiting and shortness ofbreath are majorly reported allergic reactions, back pain chest heaviness ,dyspepsia, fever, mental deposits, malignant ascites are most minorly reported. Ondansetron is most commonly used drug for vomiting whereas Hydrocortisone and Pheniramine are most commonly used drugs for shortness of breath. Adverse effects are reported mainly based on Paclitaxel drug but they are not based on dose of the drug.

Keywords: Paclitaxel, chemotherapeutic agent, Adverse effects, carcinoma

INTRODUCTION

Cancer is a large group of diseases that can start in almost any organ or tissue of the body when abnormal cells grow uncontrollably, go beyond their usual boundaries to invade adjoining partsof the body and/or spread to other organs. Cancer is the leading cause of death worldwide accounting for nearly 10million deaths in 2020. Adverse drug reaction: an adverse drug reaction can be defined as an appreciably harmful orunpleasant reaction resulting from an intervention related to the use of a medicinal product.

Paclitaxel injection is an anti-cancer chemotherapy drug sold

under brand name TAXOL. It is a tetracyclic triterpenoid which is isolated originally from bark of TAXUS BREVIFOLIA. Paclitaxel is a white to off-white crystalline powder with empirical formula C47H51NO14 and molecular weight of 853.9.it is highly lipophilic, insoluble in water, melts at around 216-217˚C. It is a clear, colourless to slightly yellow viscous solution. To enter in to blood stream intravenously paclitaxel is mixed with solvents. Before administration of paclitaxel, steroids are usually taken to minimize the reactions to the solvents. Paclitaxel is one of the widely employed anticancer drugs as a first line and predominantly usedsubsequent therapy for the head and neck cancer, restriction of breast, cervical cancer, and unknown primary lung cancer with histopathological proof of cancer.

MATERIALS AND METHODS

Study Methodology

Study Design: Retrospective, observational study, single centered study
Study Population: 100.
Study Duration: February 2020-february 2021

Inclusion Criteria

Age limit between 18-80 years. Neo adjuvant /adjuvant /metastasis setting surgical treatment with histological complete resection(RO) of breast, ovary cancer, head and neck cancer, cervical cancer, unknown primarylung with histopathological proof of cancer. Performance status index >80%.

Exclusion Criteria

Severe and relevant comorbidity that would interact with the application of cytotoxic agents orthe participation in the study. History of any prior allergic/anaphylactic reaction to drugs and associated solvents.

Study Procedure

A retrospective study was conducted to find the incidence of adverse reactions of paclitaxel incancer patients. The data will be conducted from patient's records and documented on data collection form designed for the study.
Expected outcomes: rate of incidence of adverse effects occurring in cancer patients who aretreated with paclitaxel drug.

RESULTS

Table 1: Depiction of Adverse Effects in Cancer Patients

ADVERSE EFFECTS	NO.PATIENTS
NOT REPORTED	38
REPORTED	62
TOTAL	100

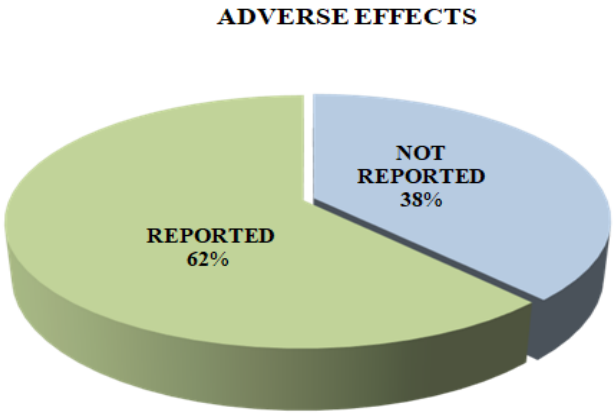


Fig 1: Depiction of adverse Effects in Cancer Patients

In our study out of 100 Patients, 62 % patients were Reported Adverse Effects and 38% patientsNot Reported Adverse Effects.

Table 2: Distribution of Patients Based on Gender

GENDER	NO.OF PATIENTS
FEMALE	95
MALE	5
TOTAL	100

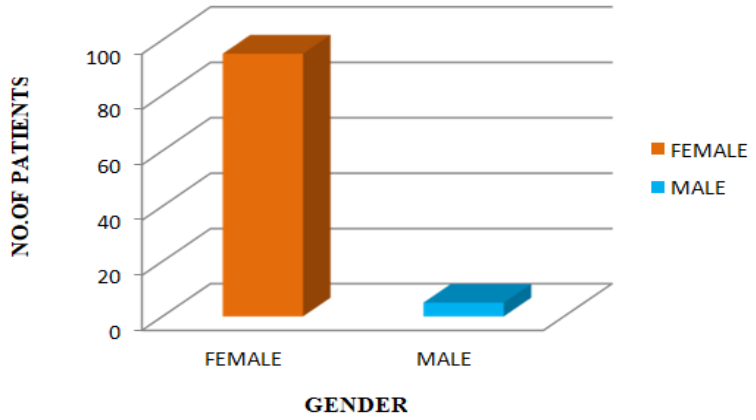


Fig 2: Distribution of Patients Based on Gender

In our study out of 100 patients, 95% of Patients are Female and 5% of patients are Male.

Table 3: Distribution of Patients Based on Age

AGE	NO.OF PATIENTS
<20	0
21-30	1
31-40	8
41-50	31
51-60	37
61-70	19
71-80	4
TOTAL	100

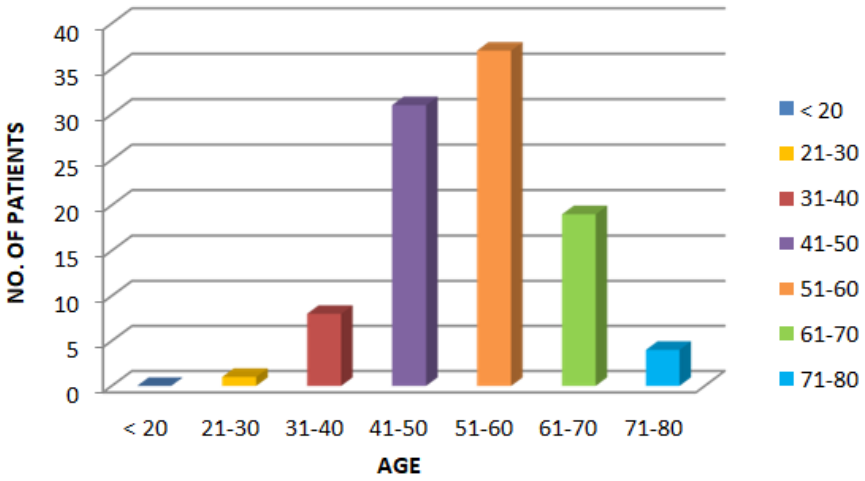


Fig 3: Distribution of Patients Based on Age

In our study out of 100 patients. The age group between 51-60 (37 patients) is more in number followed by age group 41-50 (31 patients).

Table 4: Distribution of Patients Based on Weight

WEIGHT(kgs)	NO.OF PATIENTS
30.5-40.5	1
40.6-50.5	15
50.6-60.5	29
60.6-70.5	34

70.6-80.5	17
80.6-90.5	4
TOTAL	100

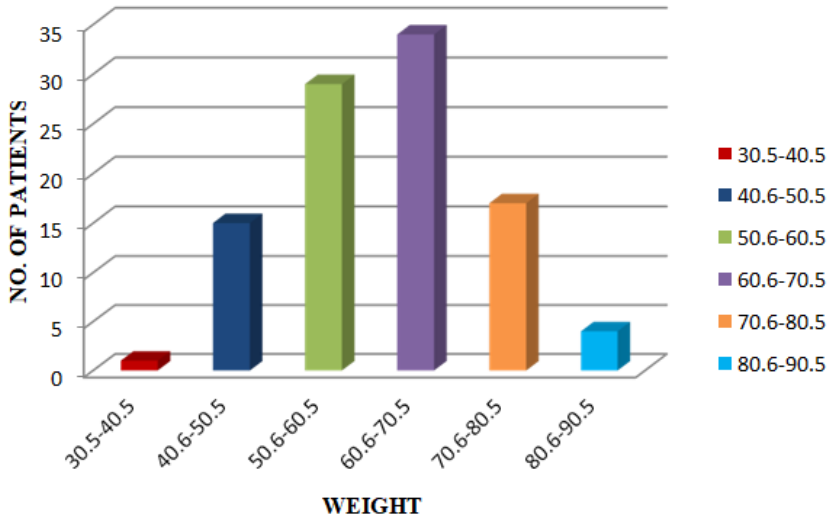


Fig 4: Distribution of Patients Based on Weight

In our study out of 100 patients, we found that more number of patients having weight about 60.6 kgs to 70.6 kgs followed by 50.6kgs to 60.5kgs.

Table 5: Distribution of Patients Based on Body Mass Index

BMI	NO. OF PATIENTS
< 18.5 (underweight)	3
18.5-24.9 (normal weight)	34
25.0-29.9(over weight)	43
30.0-34.9(obese)	16
>35(extreme obese)	4
TOTAL	100

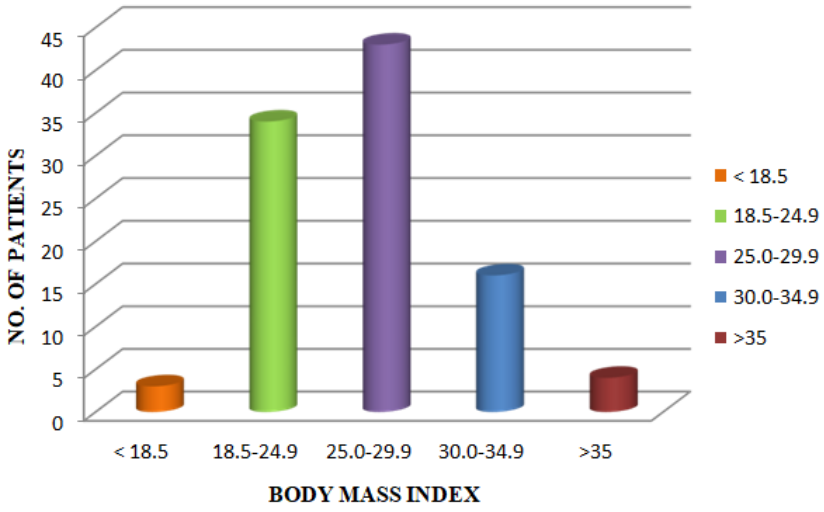


Fig 5: Distribution of Patients Based on Body Mass Index

In our study out of 100 patients, over weight (25.0 kg/m2 – 29.9 kg/m2) patients are more in number followed by normal weight (18.5 kg/m2 – 24.9 kg/m2).

Table 6: Distribution of Patients Based on Dose

DOSE (MG)	NO. OF PATIENTS
100-150	2
151-200	6
201-250	19
251-300	56
> 300	17
TOTAL	100

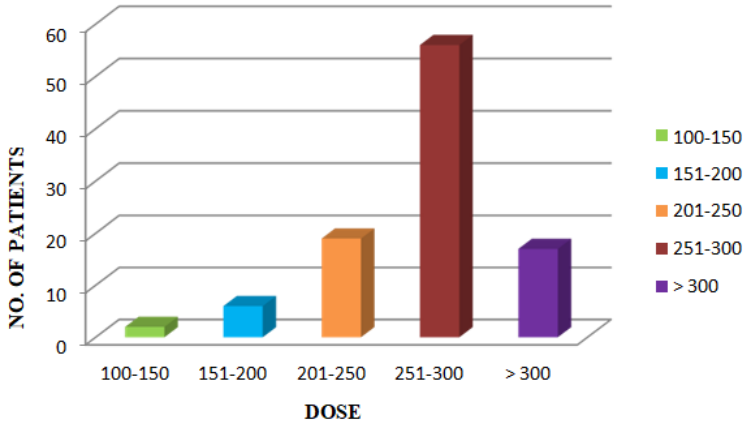


Fig 6: Distribution of Patients Based on Dose

In our study out of 100 patients, the dose of 251mg – 300 mg were more in number.

Table 7: Distribution of Adverse Effects Based On Dose

DOSE	AEs NOT REPORTED	AEs REPORTED
100-250	11	16
251-299	17	23
>300	10	23
TOTAL	38	62

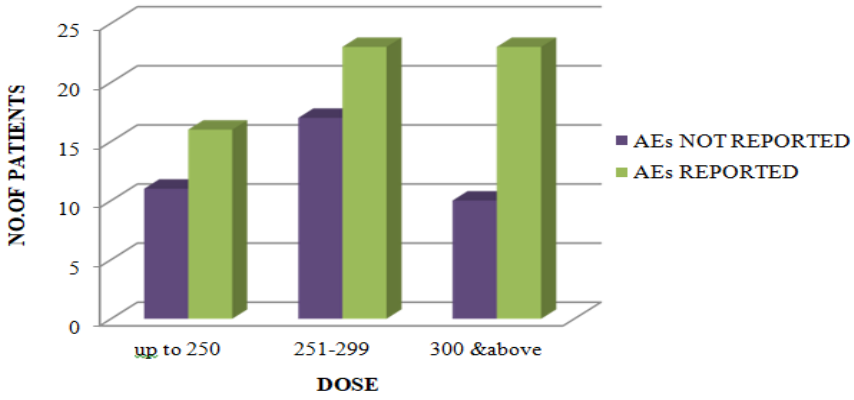


Fig 7: Distribution of Adverse Effects Based On Dose

Out of 100 patients, adverse effects are highly reported in 46 patients with a dose of 251 mg to >300 mg and adverse effects are not reported in 10 patients with a dose of >300mg.

Table 8: Distribution of Patients Based On Carcinoma

CARCINOMA	NO.PATIENTS
Breast	34

Ovary	36
Others	30
Total	100

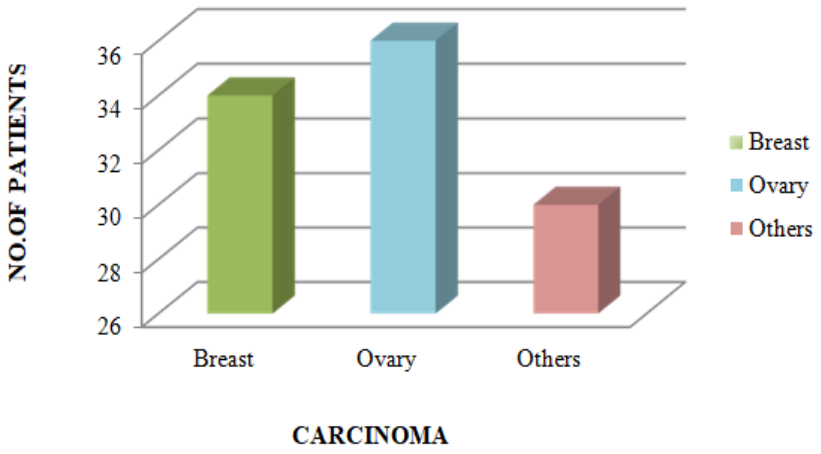


Fig 8: Distribution of Patients Based On Carcinoma

Table 9: Distribution of Adverse Effects Based On Carcinoma

TYPE OF CARCINOMA	AEs NOT REPORTED	AEs REPORTED
Ovary	14	20
Breast	12	24
Others	12	18
TOTAL	38	62

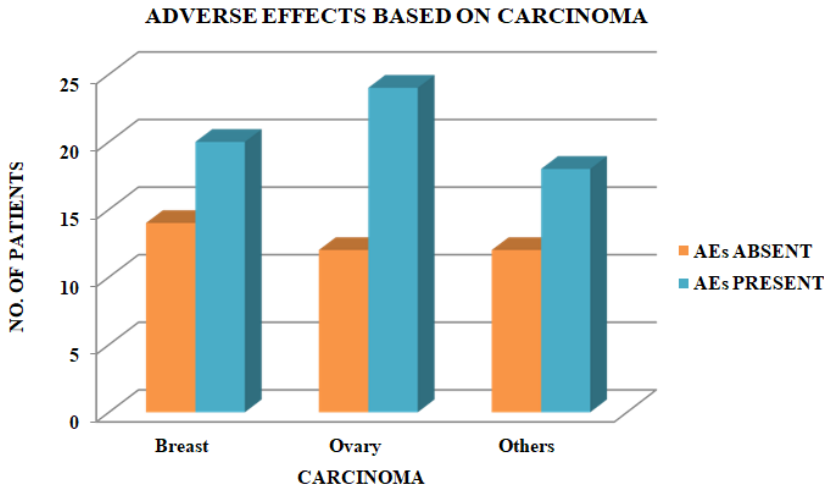


Fig 9: Distribution of Adverse Effects Based on Carcinoma

Table 10: chi square test for adverse effects and carcinoma

Chi square test	Value	df	P value
Pearson Chi-Square	0.529a	2	0.767

Table 11: Distribution of Adverse Effects in Gender

GENDER	AEs NOT REPORTED	AEs REPORTED
Female	35	60
Male	3	2
TOTAL	38	62

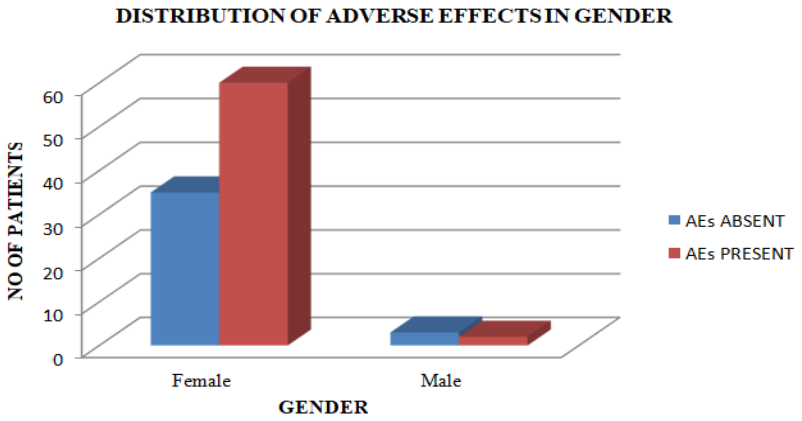


Fig 10: Distribution of Adverse Effects Based on Gender

Table 12: Mean + Standard Deviation Values of Age, Height, Weight, Bsa, BMI By Dose

VARIABLE	DOSE MEAN + STANDARD DEVIATION		
	100-250	**251-299**	**>300**
AGE	52.26 + 7.214	55.4 +10.172	52.53 +9.411
HEIGHT	152.981+ 4.673	153.753+7.536	154.848+6.457
WEIGHT	53.523 + 9.498	61.1728+5.988	70.617+10.673
BSA	1.5078+0.163	5.5175+24.56	1.6897+0.175
BMI	22.889+3.694	26.06+ 3.74	29.294+ 4.647

DISCUSSION

ANOVA Test Results

VARIABLE		SUM OF SQUARE	D.F	MEAN SQUARE	F VALUE	P VALUE
AGE	Between group	214.823	2	107.41	1.267	0.286
	Within group	8222.967	97	84.773		
	Total	8437.79	99			
HEIGHT	Between group	53.333	2	26.667	0.63	0.535
	Within group	4108.443	97	42.355		
	Total	4161.77	99			
WEIGHT	Between group	4412.90	2	2206.4	28.961	0
	Within group	7390.156	97	76.187		
	Total	11803.06	99			
BSA	Between group	367.343	2	183.67	0.757	0.472
	Within group	23538.041	97	242.66		
	Total	23905.38	99			
BMI	Between group	612.184	2	306.09	18.647	0
	Within group	1592.2	97	16.415		
	Total	**2204.4**	**99**			

CONCLUSION

According to our study, 68 ADRs were reported and 32 were not reported, with 95 females and 5 males being most affected with cancer between the ages of 51 and 60, and 260 mg of paclitaxel being the most commonly used. Patients experienced shortness of breath, which was followed by nausea and vomiting. On administration of the paclitaxel drug, 68% ADRs were reported, with vomiting and shortness of breath being the most commonly reported allergic reactions, followed by back pain, chest heaviness, dyspepsia, fever, mental deposits, and malignant ascites. The most commonly used drug for vomiting is ondansetron, while the most commonly used drugs for shortness of breath are hydrocortisone and pheniramine. Adverse effects are mostly reported with the Paclitaxel drug, but not with the dose.

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