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AN APPROACH TO TOXICITY PROFILE INDUCED BY CHEMOTHERAPY: ADR'S EVALUATION AN OBSERVATIONAL STUDY

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INTRODUCTION

1. CANCER

It is characterized by the development of abnormal cells which proliferate uncontrollably and also have the ability to kill the normal body tissue by consuming the nutrients and blood and other essentials without allowing them to use. Cancer often in a majority it has the ability to spread throughout the body.

2. CHEMOTHERAPY

Chemotherapy is the use of chemical substance to cure cancer. These chemical agents intend in inhibiting their growth or by killing the malignant form cancer cells. These chemotherapy agents are directly administered into veins.

3. ADVERSE REACTION

Any unpleasant or undesired reaction in response to the drug. The outbreak of these adverse effects may be immediate or develop over sometime lapse.

Also called an adverse drug event (ADE), adverse drug reaction (ADR), adverse effect or adverse event.

Chemotherapy toxicity is an often and it's a consequence of therapy that can occur even at pharmacological doses. Chemotherapeutic agents kill rapidly growing cells. In general chemotherapy acts by damaging the DNA and causing other mechanisms to inhibit DNA synthesis finally results in killing the tumor cells, however they can affect normal, healthy cells that are rapidly growing.

The normal cells that are most likely affected by chemo involves:

- Blood-forming cells in the bone marrow,
- Hair follicles, Cells in G.I tract and reproductive system

When damage to these cells occur, toxicity will ensue. Some of these may seek emergency care and some are sought for supportive care. This study will not talk about all toxicities, it only discusses about the toxicities that are discover in the hospital settings and it's grading according to NCI-CTCAE(National Cancer institute - Common terminology criteria for Adverse events). Chemotherapy agents are commonly associated with ADR'S due to their mechanism of action in body. Common toxicities associated with these agents include myelosuppression, mucositis, nausea, vomiting, diarrhea, alopecia, fatigue, skin toxicity etc.

The chemotherapeutic agents induced toxicity includes as following

- Cardiotoxicity – Hypertensive crisis, LV Dysfunction, heart failure.

Agents: alkylating agents, 5FU, paclitaxel, anthracyclines, trastuzumab etc

- Pulmotoxicity – ILD, pleural effusion, pneumonitis, pneumothorax.

Agents: Dacarbazine, Bleomycin, 5FU, MTX, vinblastine, nivolumab, pembrolizumab, cyclophosphamide.

- G.I toxicity – Nausea, vomiting, mucositis, diarrhoea, constipation, dysgeusia.

Agents : taxanes, anthracyclines, platinum compounds, 5FU, MTX, melphalan, irinotecan

- CNS toxicity – Intracranial haemorrhage, Encephalopathy, Seizures, Stroke etc

Agents : carmustine, cisplatin, carboplatin, cytarabine, 5FU, Ifosfamide, busalfan.

- Nephrotoxicity- Acute kidney injury.

Agents : Platinum compounds, Ifosfamide, gemcitabine, mitomycin, MTX, cetuximab.

- Skin Toxicity- skin rash, pruritis, hyperpigmentation, dry skin.

Agents: Gemcitabine, capecitabine, cyclophosphamide, docetaxel, rituximab, anthracyclines, paclitaxel, Imatinib, dasatinib.

- Bone marrow toxicity – Myelosuppression

Agents: Alkylating agents, pyramidina analogs, anthracyclines, MTX, hydroxyurea.

Other toxicities

- Alopecia – Alkylating agents, Taxanes, Anthracyclines, Antimetabolites, Target agents- cetuximab, erlotinib etc.
- Peripheral Neuropathy: Taxanes, platinum compounds, vincristine, bortezomib, thalidomide.
- Anaphylaxis – Platinum compounds, Taxanes, asparaginase, rituximab, trastuzumab, cetuximab.
- Extravasation – cisplatin, anthracyclines, bleomycin, taxanes, docetaxel.
- Infusion related reactions – Paclitaxel, Rituximab,
- Hand and Foot Syndrome – Capecitabine, gemcitabine, 5FU, doxorubicin.

Diagnosis

ASSESSMENT OF CHEMOTHERAPY TOXICITY

The Common Terminology Criteria for Adverse Events (CTCAE) is widely accepted throughout the oncology community as the standard classification and severity grading scale for adverse events in cancer therapy and other oncology settings. The National Cancer Institute issued the Common Terminology Criteria for Adverse Events (CTCAE). These measures rely upon patient self-reporting which consists of five graded scores which are the weighted sums of the questions in their section.

Methodology

- Study Ste - Outpatient department of oncology, tertiary care hospital, Kakinada, Andhra Pradesh.
- Study Duration - Six months
- Sample Size - 224
- Study Design – Prospective study

Inclusion Criteria

- Patients who are undergoing chemotherapy with all type of cancers.
- Consider both the genders and pediatrics, adults, geriatrics.
- Patients with history of radiation and chemotherapy.
- Patients with co-morbidities like hypertension, diabetes
- Considering both the single and combination regimens.

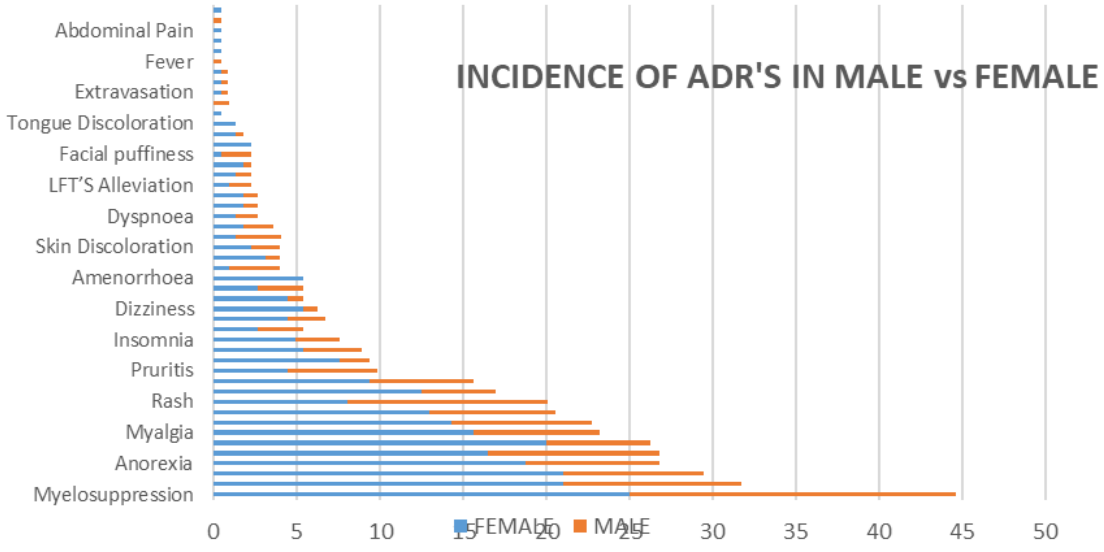
RESULTS

1. INCIDENCE OF ADR'S: In this study, 224 population were taken. Among them 48 unwanted effects were observed and noted in below table. In table-1 unwanted effects were counted in each patient and calculate percentage of each effect

Table 1: Incidence of Adr's Induced By Chemotherapy In Cancer Patients.

S.NO	ADVERSE DRUG REACTIONS	FREQUENCY	PERCENTAGE
1	Myelosuppression	100	44.64
2	Alopecia	71	31.68
3	Dysgeusia	66	29.46
4	Anorexia	60	26.46
5	Fatigue	60	26.46
6	Peripheral Neuropathy	59	26.33
7	Myalgia	52	23.21
8	Diarrhoea	51	22.76
9	Nausea	46	20.53
10	Rash	45	20.08
11	Vomiting	38	16.96
12	Constipation	35	15.62
13	Pruritis	22	9.82
14	Infusion Related Reactions	21	9.37
15	Flatulence	20	8.92
16	Insomnia	17	7.59
17	Mucositis	15	6.69

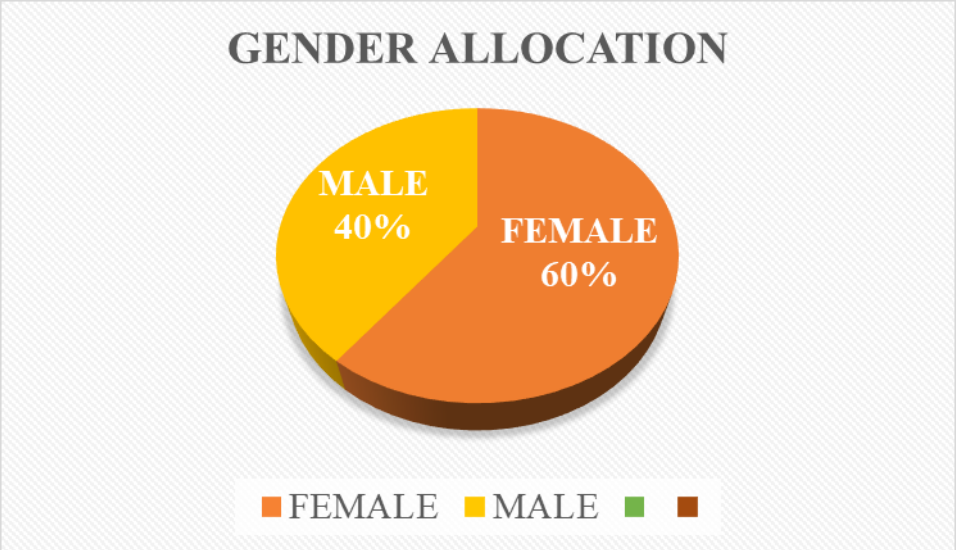
18	Nail Discoloration	15	6.69
19	Dizziness	14	6.25
20	Dyspepsia	12	5.35
21	**Fairness**	**12**	**5.35**
22	Amenorrhoea	12	5.35
23	Dry Skin	9	4.01
24	Headache	9	4.01
25	Skin Discoloration	9	4.01
26	Cough	9	4.01
27	Hand Foot Syndrome	8	3.57
28	Dyspnoea	6	2.68
29	Oedema	6	2.68
30	RFT Alleviation	6	2.68
31	LFT Alleviation	5	2.23
32	Arthralgia	5	2.23
33	Hypocalcaemia Features	5	2.23
34	Facial puffiness	5	2.23
35	LV Disfunction	5	2.23
36	Weight loss	4	1.78
37	Tongue Discoloration	3	1.34
38	Hiccups	3	1.34
39	Vein Discoloration	2	0.89
40	Back pain	2	0.89
41	Extravasation	2	0.89
42	DVT	2	0.8
43	Fever	1	0.44
44	Unconscious	1	0.44
45	Loss of speech	1	0.44
46	Abdominal Pain	1	0.44
47	Hyperlipidaemia	1	0.44
48	Aggressiveness	1	0.44



GENDER ANALYSIS:- A total study population of 224 patients has been assessed for the study. Among these population majority were of females constituting of 60.26% (n=135) and males of 39.74% (n=89).

TABLE 2.

Gender	Frequency	Percent
Male	89	39.74
Female	135	60.26
Total	224	100.0



AGE DISTRIBUTION:- According to the study in the study population the highest population were between ages of 40-49 years constituting of 37%(n=83) and lowest age group of age below 10-19 years constituting of 0.89% (n=2).

Table 3.

Age	Frequency	Percentage
0-9	3	1.34
10-19 years	2	0.89
20-29years	5	2.23
30-39 years	30	13.38
40-49 years	83	37.05
50-59 years	57	25.40
60-69 years	38	16.96
70-79years	6	2.67
Total	224	100.0

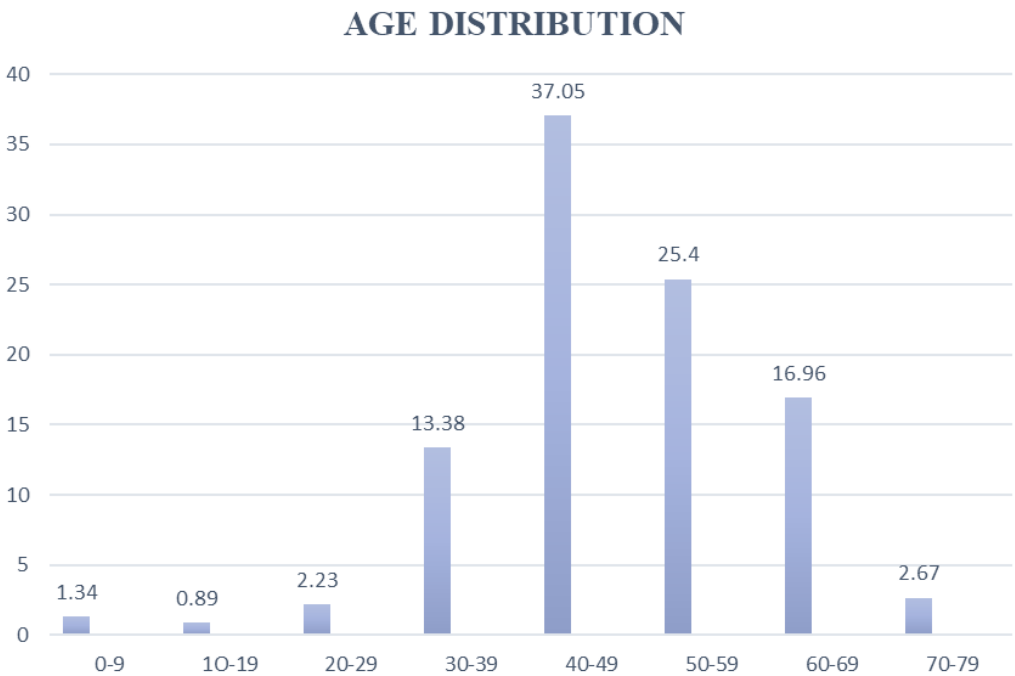


Fig No. 3: Age Distribution in study population.

AGE GENDER DISTRIBUTION:- According to the study the mean value of age gender distribution of the patients included in the study.

TABLE 4.

AGE	MALE	FEMALE	MEAN
0-9	2	1	1.5
10-19	2	0	1
20-29	2	3	2.5
30-39	6	24	15
40-49	29	54	41.5
50-59	24	33	28.5
60-69	19	19	19
70-79	5	1	3
Total	89	135	112

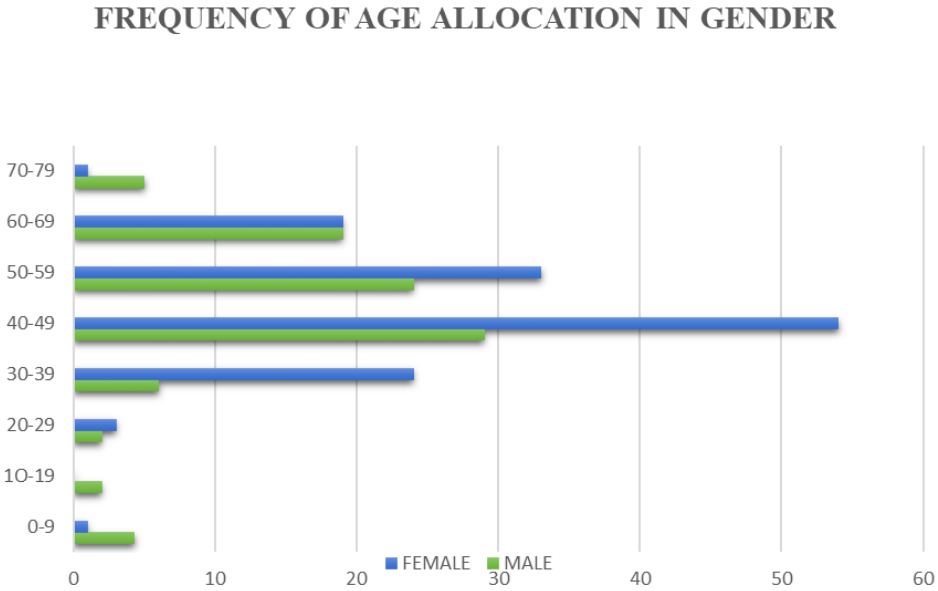
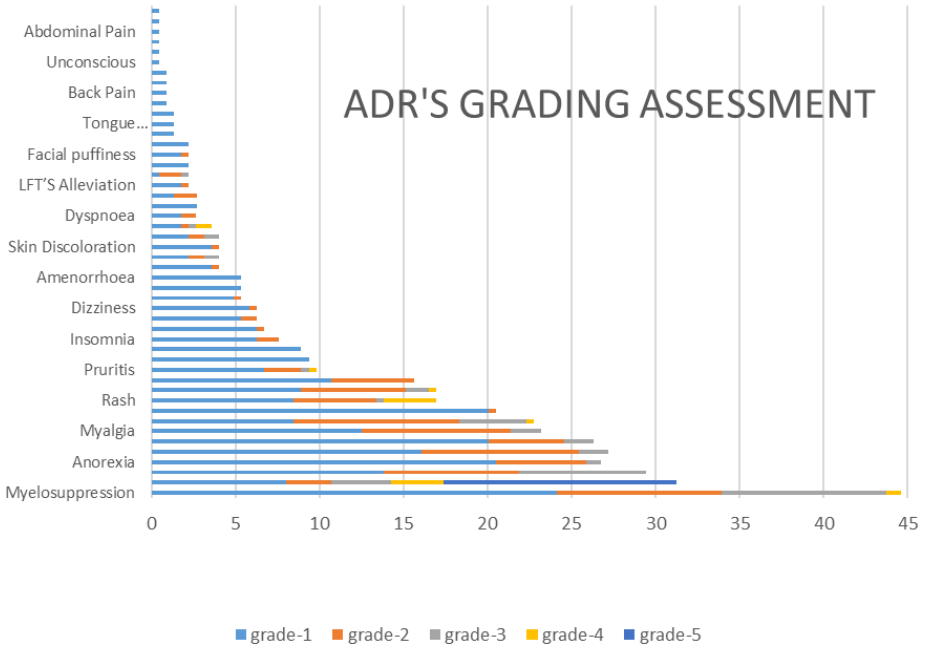


FIG. 4: Age-Gender distribution among study population.

GRADE ASSESMENT: According to the Common Terminology Criteria for Adverse Events (CTCAE), Grading of the adverse reactions is assessed as grade-1, grade-2, grade-3, grade-4, grade-5.

S.No	ADR'S	Grade-1		Grade-2		Grade-3		Grade-4		Grade-5		Total (No.)
		Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
1	Myelosuppression	54	24.10	22	9.8	22	9.82	2	0.89			100
2	Alopecia	18	8.03	6	2.68	8	3.57	7	3.12	31	13.83	70
3	Dysgeusia	31	13.83	18	8.03	17	7.58					66
4	Anorexia	46	20.53	12	5.35	2	0.89					60
5	Fatigue	36	16.07	21	9.37	4	1.78					61
6	Peripheral Neuropathy	45	20.08	10	4.46	4	1.78					59
7	Myalgia	28	12.49	20	8.92	4	1.78					52
8	Diarrhoea	19	8.48	22	9.82	9	4	1	0.44			51
9	Nausea	45	20.08	1	0.44							46
10	Rash	26	8.48	11	4.91	1	0.44	7	3.12			45
11	Vomiting	20	8.92	14	6.24	3	1.34	1	0.44			38
12	Constipation	24	10.71	11	4.91							35
13	Pruritis	15	6.69	5	2.23	1	0.44	1	0.44			22
14	Infusion Related Reactions	21	9.37									21
15	Flatulence	20	8.92									20
16	Insomnia	14	6.25	3	1.34							17
17	Mucositis	14	6..25	1	0.44							15

18	Nail Discoloration	12	5.35	2	0.89							14
19	Dizziness	13	5.80	1	0.44							14
20	Dyspepsia	11	4.91	1	0.44							12
21	Fairness	12	5.35									12
22	Amenorrhoea	12	5.35									12
23	Dry Skin	8	3.57	1	0.44							9
24	Headache	5	2.23	2	0.89	2	0.89					9
25	Skin Discoloration	8	3.57	1	0.44							9
26	Cough	5	2.23	2	0.89	2	0.89					9
27	Hand Foot Syndrome	4	1.78	1	0.44	1	0.44	2	0.89			8
28	Dyspnoea	4	1.78	2	0.89							6
29	Oedema	6	2.68									6
30	RFT Alleviation	3	1.34	3	1.34							6
31	LFT Alleviation	4	1.78	1	0.44							5
32	Arthralgia	1	0.44	3	1.34	1	0.44					5
33	Hypocalcaemia Features	5	2.23									5
34	Facial puffiness	4	1.78	1	0.44							5
35	Weight loss	3	1.34			1	0.44					4
36	Tongue Discoloration	3	1.34									3
37	Hiccups	3	1.34									3
38	Vein Discoloration	1	0.44	1	0.44							2
39	Back pain	1	0.44	1	0.44							2
40	Extravasation	2	0.89									2
41	DVT	2	0.89									2
43	Fever	1	0.44									1
44	Unconscious	1	0.44									1
45	Loss of speech	1	0.44									1
46	Aggressiveness	1	0.44									1
47	Hyperlipidaemia	1	0.44									1
48	Abdominal pain	1	0.44									1



CHEMOTHERAPY DRUGS: In this study, 27 single and 30 combination regimens were given to patients with cancer and noted the individual drug frequencies below in table-6.

Table 6: Frequency of Single and Combination Regimen of Chemotherapy.

S.NO	SINGLE REGIMEN	FREQ	%	COMBINATION REGIMEN (%)	FREQ	%
1	Pemetrexed	1	0.44	Pemetrexed + Carboplatin	6	2.68
2	Gefitinib	2	0.89	Paclitaxel + Carboplatin	24	10.71
3	Bortezomib	1	0.44	Gemcitabine + Cisplatin	3	1.34
4	Ifosfamide	4	1.78	Paclitaxel + Carboplatin + Erlotinib	1	0.44
5	Imatinib	18	8.03	Ac Regimen	14	6.25
6	Dasatinib	4	1.78	Tch Regimen	5	2.23
7	Lenalidomide	6	2.68	Ac Regimen + Paclitaxel	1	0.44
8	Vincristine	2	0.89	Trastuzumab + Paclitaxel	1	0.44
9	Gemcitabine	2	0.89	Bortezomib + Lenalidomide + Dexamethasone	2	0.89
10	Capecitabine	5	2.23	Ifosfamide + Doxorubicin	2	0.89
11	Decitabine	3	1.34	Gemcitabine + Oxaliplatin	2	0.89
12	Nilotinib	1	0.44	Capecitabine + Oxaliplatin	4	1.78
13	Sunitinib	3	1.34	Gemcitabine + Capecitabine	1	0.44
14	Erlotinib	26	11.6	Irinotecan + Oxaliplatin	2	0.89
15	Cetuximab	1	0.44	Docetaxel+Oxaliplatin+5 FU	2	0.89
16	Rituximab	6	2.68	Gemcitabine + Carboplatin	2	0.89
17	Carboplatin	3	1.34	R-Chop Regimen	5	2.23
18	Oxaliplatin	2	0.89	Ac Regimen + Ifosfamide	1	0.44
19	Melphan	1	0.44	Bortezomib + Lenalidomide	3	1.34
20	Axitinib	1	0.44	Bendamustine + Rituximab	1	0.44
21	Rucaparib	1	0.44	Docetaxel + Oxaliplatin	1	0.44
22	Hydroxyurea	1	0.44	Bortezomib + Cyclophosphamide	1	0.44
23	Trastuzumab	4	1.78	Pertuzumab +Paclitaxel	1	0.44
24	Paclitaxel	21	9.37	Docetaxel + Cyclophosphamide	4	1.78
25	Docetaxel	6	2.68	Lapatinib + Capecitabine	1	0.44
26	5 Fluorouracil	2	0.89	Lenalidomide + Zolendric Acid	1	0.44
27	Bendamustine	1	0.44	Cetuximab + Irinotecan	1	0.44
28				Irinotecan + Capecitabine	1	0.44
29				Eox Regimen	3	1.34
30				Epirubicin + Cyclophosphamide	1	0.44
	Total	128	57.1		96	42.9

CONCLUSION

Cancer is one of the diseases which are developing very rapidly throughout the world due to which mortality rate is also going to increase world widely. Chemotherapy is the most widely used treatment for a large number of cancer types. Earlier these chemotherapeutic drugs were considered to be quite targeted and selective for tumor cells, but now it is a well-known that chemotherapy also damages the normal cells, which leads to various side effects and in some cases even deaths reported. These side effects include Myelosuppression-44.64% Alopecia-31.68% Dysgeusia-29.46% Anorexia-26.46% Fatigue-26.46% Peripheral Neuropathy-26.33% Myalgia-23.21% Diarrhoea-22.76% Nausea-20.53% Rash-20.08%. The last ten ADR'S in this study were include Aggressiveness-0.44% Hyperlipidaemia-0.44% Abdominal Pain-0.44% Loss of Speech-0.44% Unconscious-0.44% Fever-0.44% Back Pain-0.89% Vein Discoloration-0.89% Extravasation-0.89% DVT-0.89%

In this study we have evaluated the incidence of ADR'S experienced by patients undergoing chemotherapy in a clinical practice setting, rather than in the clinical trials. It has advantage that looking across a range of cancers and treatment regimens to identify the ADR'S experienced by patients who are undergoing chemotherapy. In this study, the majority of patients experienced multiple ADR'S and at least 46% of patients had one severe side effect. Many patients experienced mild ADR'S continuously throughout the period of therapy in this study.

In this study we found 48 types of ADR'S that patients experienced during the chemotherapy. Among them, some are mild, moderate and serious. Some patients discontinued the chemotherapy agents because of experiencing a serious ADR'S and undergoes for alternative therapy or held the offending agent for some time to recover and done a rechallenge.

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