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Research Article

Assessment of Adverse Drug Reactions (Anti Virals & Anti-Diabetics) in a Tertiary Care Hospital – Nellore

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Abstract

Pharmacovigilance target towards signal detection, creating warning, restricting drug use, sometimes withdrawal of drug from market & finally decreasing mortality & risk of ADRs in patients. The present study was conducted in the Department of General medicine, AC Subba Reddy Government Medical College and tertiary care teaching hospital, Nellore, Andhra Pradesh. The study was conducted for four months from December 2022 to March 2023. The study was retrospective, non-interventional and observational type, as a part of routine post-marketing surveillance. On WHO causality scale, causality of maximum ADRs was possible (92.45 %) followed with probable, in line with study of Patel et.al (2015) but in contrary to Gungam et.al (2018). As per Rawlins and Thompson's classification Type A ADRs account for 48.11 % followed by Type -C (41.51%), type- B and no case of Type -D, E,F. Severity of ADRs as per Hartwig's scale was found to be of mild category (100%) in line with Gungam et al study. More precise side effects data on these drugs will help in reducing the ADRs burden and ascertain patient safety.

Keywords: Pharmacovigilance, Hartwig's scale, post-marketing surveillance, ADRs.

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1. Introduction

Thalidomide disaster is one of the overturn jolts in the field of allopathic medicine that attracted the attention of practitioner all over the world towards adverse effects of

drugs, and then only the actual concept of monitoring of adverse drug reactions came into limelight. United Kingdom firstly introduced the yellow card for adverse

drug reaction reporting. From 2010 pharmacovigilance started in India with full-fledged. Presently Indian pharmacopoeia commission (IPC) work as national coordinating Centre for pharmacovigilance program of India (PvPI), accountable for collection, assessment of reported ADRs from the various adverse drug reaction monitoring centers & pharmaceutical companies, also consulting central drug standard control organization (CDSCO) in generation of signal. IPC is also collaborating in World health organization (WHO) drug safety program. Main source of ADRs data collection is based on spontaneous reporting technique & mainly from healthcare professionals. For drugs, IPC- suspected ADRs reporting form for healthcare Professionals was used in reporting ADRs by doctors. IPC- has currently availed the ADRs reporting form for patient in English & local languages. National institute of biological has availed the form for Haemovigilance. Pharmacovigilance target towards signal detection, creating warning, restricting drug use, sometimes withdrawal of drug from market & finally decreasing mortality & risk of ADRs in patients.

Pharmacovigilance

When a novel drug is in market, it is always being supervised by pharmacovigilance centers of concerned country for the identification of adverse effects of the drug. According to WHO definition pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems¹⁻⁹. Currently, its concerns have been expanded to include:

- Herbal drugs (Herbavigilance)
- Traditional and complementary medicines
- Blood products (Haemovigilance)
- Biological (Biovigilance)
- Medical devices (Materiovigilance)
- Vaccines.

The process of pharmacovigilance starts before the marketing of new drugs and proceed along the post-marketing phase (phase IV) of drugs till it's marketed. The prime objective of ADR monitoring is to reveal the quality and frequency of ADRs and to recognize the responsible risk factors that can produce the adverse reactions.

Signal can be considered as any new safety finding within safety data which further needs investigation. Signals can be categorized into three classes: Confirmed signals, only when data shows the causal relationship between the drug and the AE; refuted / false signals where no causal relationship exists; and unconfirmed signals where further investigation required (having much more data). Preferably, the ultimate goal of signal detection is to identify unexpected ADRs and generate guidance document for labelling of pharmaceutical product that will minimize the risk of using the drug in a specified patient population (12).

Spontaneous reporting methodology

The spontaneous systems of ADRs reporting were developed only after the thalidomide disaster with the aim to regulate and control the safety of drugs. This system is helpful in the collection of post-marketing data related with safety of drugs and providing guidance in generation of safety signals. Accordingly, this system is used for identification of drug signals of new, rare and serious ADRs. This system makes simple and straightforward way for physicians, patients and pharmacists to report suspected ADRs to the nearest pharmacovigilance Centre. Adverse event report for an individual patient is source of information in pharmacovigilance is known as Individual Case Study Report (ICSR).

Causality assessment

Whenever drug therapy in patient starts chances of experiencing an adverse event is expected, it may be associated to the drug, or the illness or some other causes. Most of the time, a clear-cut 'yes/no' cause and impressive connection between a drug and the adverse event cannot be pronounced. Causality assessed on four basic specifications:

Temporal relationship: It shows how the time-sequence of the appearance of reaction is related to administration of drug.

Previous/Past knowledge: It shows whether the drug is known to cause the event/reaction in prior recipients with a certain degree of regularity.

Dechallenge: It shows whether the event declines on withdrawal the drug.

Rechallenge: It shows whether the event appeared again after again administration of drug with a gap having subsided / no events. Several times rechallenge is unethical / dangerous and is not right to conduct.

2. Methodology

Study site the present study was conducted in the Department of General medicine, AC Subba Reddy Government Medical College and tertiary care teaching hospital, Nellore, Andhra Pradesh. Duration of study The study was conducted for four months from December 2022 to March 2023. Study design The study was retrospective, non-interventional and observational type, as a part of routine post-marketing surveillance. The study did not involve direct risk to any patients no active intervention was done and not involve interviewing with patient as data was used following voluntary/spontaneous reporting system which skips requirement of patient informed consent. The confidentiality of patient was fully maintained as no name was written in reporting form, only initials were used to record data with proper case report number. Source of data ADRs reports received and collected at Pharmacovigilance unit (approved by PvPI-IPC) after Spontaneous ADR reporting mainly by doctors, other health professionals and also from patients was used as source document, over a period of 3 months.

Inclusion criteria:

- Patients who are willing to participate in the study were included.
- Patients with co morbidity condition are included
- o Patients of both the gender are included.
- Patients who are not willing to participate in the study.
- Patients with history of psychological disorders were excluded.

Exclusion criteria:

3. Results and discussion

Table 1: Demographic distribution of ADRs – Antidiabetic drugs

No. of patient	23		
No. of ADRs	30		Burden of ADRs- 1.30 ADRs per patient
Sex	No. of Patient	(%)	ADRs (%)
Male	11 (47.83%)		16 (53.33 %)
Female	12 (52.17%)		14 (46.67 %)
Age group			
Below 20 Y	0		0
20 Y- 40 Y	4 (17.39 %)		5 (16.67 %)
40 Y- 60 Y	16 (69.57 %)		20 (66.66%)
Above 60 Y	3 (13.04 %)		5 (16.67 %)

Table 2: Assessment of ADRs -antidiabetics

Causality	ADRs		%
Possible	14		46.67
Probable	16		53.33
Type of ADRs			
A	25		83.34
B	1		3.33
C	4		13.33
Severity			
Mild	30		100
Moderate	0		0
Severe	0		0
Seriousness			
Non-serious	30		100
Serious	0		0
Predictability			
Predictable	22		73.33
Not-predictable	8		26.67
Preventability			
Probably preventable	6		20
Not preventable	24		80
Outcome			
Recovered	26		80
Not recovered	4		20
Recovering	0		0
Unknown	0		0
Fatal	0		0
Organ system			
DS	14		46.67
CVS	0		0
ES	0		0

	HS	0	0
	IS	4	13.33
	LS	1	3.33
	MSS	5	16.67
	MOS	0	0
	NS	4	13.33
	RS	0	0
	US	2	6.67
Drug Therapy		No. of Patient	%
	Single drug	21	91.30
	Two drug	2	8.70
	Three drug	0	0

Table 3: List of antidiabetic drug and ADRs share

S.no.	Drug	No. of patient	No. of ADRs (%)
1.	Dapagliflozin	4	4 (13.33%)
2.	Glibenclamide	1	1 (3.33%)
3.	Glimeperide	2	3 (10%)
4.	Glimeperide+ Metformin	1	1 (3.33 %)
5.	Indapamide+Metformin	1	1 (3.33%)
6.	Saroglitazar	1	1 (3.33%)
7.	Saxagliptin	4	5 (16.67%)
8.	Sitagliptin	9	14 (46.68%)

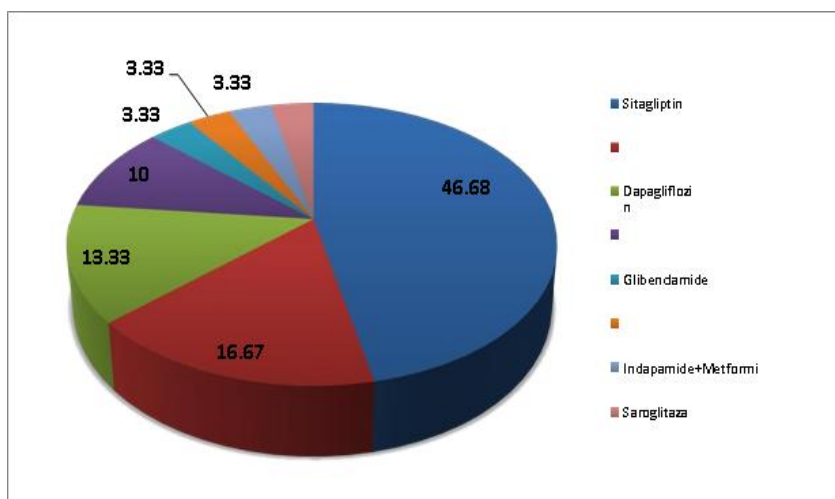


Fig 2: Percentage share of antidiabetic drugs in causing ADRs

Table 4: List of ADRs associated with antidiabetic drugs

S.no.	ADRs	No. of ADRs (n=30) %
1.	Abdominal pain	2 (6.67)
2.	Anxiety	3 (10)
3.	Pain-body	4 (13.34)
4.	Bullous pemphigoid	1 (3.33)
5.	Constipation	1 (3.33)
6.	Diarrhoea	5 (16.68)
7.	Dysuria	2 (6.67)
8.	Fatigue	1 (3.33)
9.	Headache	1 (3.33)
10.	Heartburn	1 (3.33)

11.	Increased sweating	1 (3.33)
12.	Itching	1 (3.33)
13.	Mucositis -oral	1 (3.33)
14.	Nausea	2 (6.67)
15.	Swelling	1 (3.33)
16.	Urticaria	1 (3.33)
17.	Vomiting	2 (6.67)

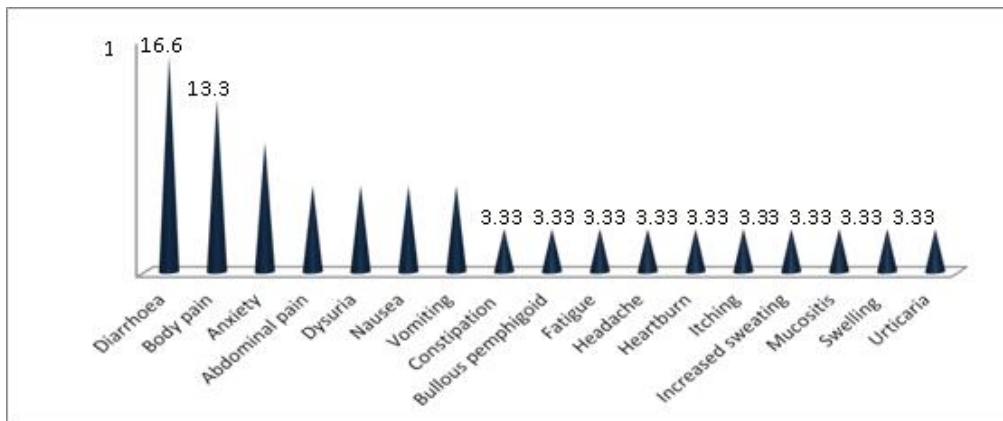


Fig 3: ADRs associated with antidiabetic

Table 5: Antidiabetic drugs-ADRs associated with different organ system

Organ System	ADRs no.	Percentage ADRs	ADRs
DS	14	46.67	Nausea-2, Vomiting-2, Diarrhoea-5, Abdominal Pain-2, Constipation-1, Mucositis-1, Heartburn-1
CVS	0	0	-
ES	0	0	-
HS	0	0	-
IS	4	13.33	Itching-1, Increased Sweating -1, Urticaria-1, Bullous Pemphigoid-1
LS	1	3.33	Generalized Swelling-1
MSS	5	16.67	Body Pain-4, Fatigue-1
MOS	0	0	-
NS	4	13.33	Headache-1, Anxiety-3
RS	0	0	-
US	2	6.67	Dysuria-2

Table 6: Demographic distribution of ADRs –Antiviral drugs

No. of patient	68		Burden of ADRs-		1.65 ADRs per patient
No. of ADRs	106				
Sex	No. of Patient %		ADRs %		
Male	36	52.94	57	53.77	
Female	32	47.06	49	46.23	
Age group					
Below 20 Y	03	4.41	4	3.77	
20 Y- 40 Y	46	67.65	73	68.87	
40 Y- 60 Y	19	27.94	29	27.36	

Above 60 Y	0	0	0	0
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Table 7: Assessment of ADRs- Antiviral drugs

Causality		ADRs	%
	Possible	98	92.45
	Probable	8	7.55
Type of ADRs			
	A	51	48.11
	B	11	10.38
	C	44	41.51
Severity			
	Mild	106	100
	Moderate	0	0
	Severe	0	0
Seriousness			
	Non-serious	106	100
	Serious	0	0
Predictability			
	Predictable	77	72.64
	Not-predictable	29	27.36
Preventability			
	Probably preventable	3	2.83
	Not preventable	103	97.17

Outcome			
	Recovered	10	9.43
	Not recovered	59	55.66
	Recovering	37	34.91
	Unknown	0	0
	Fatal	0	0
Organ system			
	DS	33	31.14
	CVS	0	0
	ES	7	6.60
	HS	7	6.60
	IS	10	9.43
	LS	2	1.89
	MSS	10	9.44
	MOS	0	0
	NS	34	32.07
	RS	3	2.82
	US	0	0
Drug Therapy			
	Single drug	9	13.24
	Two drug	0	0
	Three drug	58	85.29
	> Three drug	1	1.47

Table 8: List of antiviral drug and ADRs share

S.no.	Drug	No. of patient	No. of ADRs %
1.	Acyclovir	1	2 (1.89)
2.	Nevirapine	2	2 (1.89)

3.	TLE	38	59 (55.66)
4.	Zidovudine	6	6 (5.66)
5.	ZLE	2	3 (2.83)
6.	ZLAR	1	3 (2.83)
7.	ZLN	18	31 (29.24)

Table 9: List of ADRs associated with antiviral drugs

S.no.	ADRs	No. of ADRs % (n=106)
1.	Abdominal pain	3 (2.83)
2.	Alopecia	1 (0.94)
3.	Anaemia	7 (6.61)
4.	Anorexia	14 (13.22)
5.	Anosmia	1 (0.94)
6.	Anxiety	4 (3.77)
7.	Back pain	1 (0.94)
8.	Chest pain	2 (1.89)
9.	Constipation	1 (0.94)
10.	Diarrhoea	2 (1.89)
11.	Dizziness	11 (10.38)
12.	Drowsiness	1 (0.94)
13.	Dysphonia	1 (0.94)
14.	Fatigue	7 (6.61)
15.	Fever	2 (1.89)
16.	Flatulence	3 (2.83)
17.	Gastritis	3 (2.83)
18.	Gynaecomastia	1 (0.94)
19.	Hallucination	1 (0.94)
20.	Headache	5 (4.73)
21.	Insomnia	1 (0.94)
22.	Itching	4 (3.77)
23.	Pain -joint	1 (0.94)
24.	Lipodystrophy	1 (0.94)
25.	Hepatomegaly	1 (0.94)
26.	Myalgia	1 (0.94)
27.	Nausea	3 (2.83)
28.	Numbness-palm	1 (0.94)
29.	Rash	4 (3.77)
30.	Swelling limbs	1 (0.94)
31.	Swelling lips	1 (0.94)
32.	Tingling limbs	5 (4.73)
33.	Tingling Lips	1 (0.94)
34.	Vomiting	2 (1.89)
35.	Weight loss	6 (5.67)
36.	Xerostomia	1 (0.94)
37.	Hypersomnia	1 (0.94)

Table 10: Antiviral drugs-ADRs associated with different organ system

Organ System	ADRs no.	Percentage ADRs	ADRs
DS	33	31.14	Nausea-3,Vomiting-2, Diarrhoea-2, Abdominal Pain-3, Constipation-1, Anorexia-14, Flatulence-3, Gastritis-3,Xerostomia- 1, Mild Hepatomegaly-1
CVS	0	0	-
ES	7	6.60	Weight Loss-6, Gynaecomastia-1

HS	7	6.60	Anaemia-7
IS	10	9.44	Rash- 4, Itching-4, Alopecia-1, Lipdystrophy-1
LS	2	1.89	Swelling Limbs-1, Lip Swelling-1
MSS	10	9.44	Joint Pain-1, Fatigue-7, Back Pain-1, Myalgia-1
MOS	0	0	-
NS	34	32.07	Headache-5, Dizziness-11, Drowsiness-1, Numbness- 1, Tingling Limbs-5, Tingling Lips-1, Insomnia-1, Hypersomnia-1, Anosmia-1, Hallucination-1, Fever-2, Anxiety-4
RS	3	2.82	Chest Pain-2, Dysphonia-1
US	0	0	-

Collection of Plant:

A total of 23 patients encountered 30 ADRs therefore burden of ADRs per patient were found to be 1.30 (Table 2). Male patient encountered maximum ADRs (53.33%) followed by female (46.67%), similarly male predominance in studies of Deb et.al (2017), Singh et.al (2017), but in contrary Adhikari et.al (2016) reported female predominance. Maximum ADRs occurred in age group between 40 y-60 y (66.66%), this result is in same order with study of Adhikari et al (2016) and Singh et.al (2017). Most common ADRs in our population were diarrhoea (16.68%), body pain (13.34%) and anxiety (10%) as depicted in Table 3.22 and Fig 3.9, contrary to our study Adhikari et.al (2016) reported most common ADRs as muscle pain, joint pain and fatigue, Deb et.al(2017) reported dyspepsia, hypoglycemia & diarrhoea. Most common drug leading to maximum ADRs was sitagliptin (9, 46.68 %) followed by saxagliptin (16.67%), whereas Adhikari et.al(2016) and Deb et.al(2017) reported metformin as most responsible drug for ADRs¹⁰⁻¹⁵.

On WHO causality scale causality of maximum ADRs were probable (88.24 %) followed with possible whereas Singh et.al(2017) reported ADRs mostly of possible type followed by probable. As per Rawlins and Thompson's classification Type-A ADRs account for 83.34 % followed by Type –C (13.33%), Type- B (3.33%) and no case of Type –D, E, F. Severity of ADRs as per Hartwig's scale was found to be of mild category (100%), this was in line with study of Singh et.al(2017). All ADRs cases were of non-serious nature (100%). As per CIOMS most ADRs are of predictable type (73.33 %) and on preventability- as per Schumock & Thornton criteria most ADRs are not-preventable type (80%). ADRs mostly involved digestive system (46.67%) followed by Musculo-skeletal system (16.67%). In contrary to our study Adhikari et.al (2016) reported musculo-skeletal system as most affected organ system, Singh et.al (2017) reported endocrine system followed by digestive system. In most of case single drug therapy was given to patient accounting - 91.30 % among whole population receiving antidiabetic drug (Table 3).

DS-Digestive system, CVS-cardio-vascular system, ES-Endocrine system , HS-Hematological system, IS-Integumentary system, LS-Lymphatic system, MSS-Musculoskeletal system, MOS-Multi- organ system, NS-Nervous system, RS-Respiratory system, US-Urinary system. Most prevalent organ system affected with antidiabetic drugs was digestive system accounting 46.67% of total ADRs cases followed by ADRs of musculoskeletal system (16.67%), Nervous system & integumentary system each with 13.33%, with no ADRs of ES, CVS, MOS, RS & HS. Among DS most common ADRs were diarrhoea, nausea, vomiting and abdominal pain, among MSS ADRs body pain and vomiting were common.

A total of 68 patients encountered 106 ADRs, therefore burden of ADRs per patient was found to be 1.65 as depicted in Table 7 and similar burden (1.66) is mentioned in Patel et.al (2015) study. Male patient encountered with maximum ADRs (53.77%) followed by female (46.23%). Contrary studies such as Patel et.al(2015) reported female predominance. Most common age group affected was between 20y-40y (68.87%), same age group is mentioned by Patel et.al(2015) as more patients with HIV are present in adult age group.

On WHO causality scale, causality of maximum ADRs was possible (92.45 %) followed with probable, in line with study of Patel et.al(2015) but in contrary to Gungam et.al(2018). As per Rawlins and Thompson's classification Type A ADRs account for 48.11 % followed by Type –C (41.51%), type- B and no case of Type –D, E,F. Severity of ADRs as per Hartwig's scale was found to be of mild category (100%) in line with Gungam et al study. All ADRs cases were of non-serious nature (100%) where as in study of Patel et.al(2015) mostly non-serious ADRs along with serious. As per CIOMS most ADRs are of predictable type (72.64 %) and on preventability- as per Schumock & Thornton criteria maximum ADRs of not-preventable type (97.17%). Patel et.al(2015) also reported maximum ADRs of not preventable type. ADRs mostly affected nervous system (32.07 %) followed by digestive system (31.14%).

Similarly Patel et.al (2015) also reported major involvement of digestive system, integumentary system and nervous system. Gungam et.al (2018) reported most affected system as hematological system, nervous system & digestive system. In most of cases three drug therapies was given to patient accounting 85.29% among whole population receiving antiviral drugs (Table 8).

4. Conclusion

ADRs associated with anti-diabetic drugs can be efficiently handled by reducing the drug dose or by withdrawing the drug¹⁶⁻¹⁷. Most common ADRs in our population were diarrhea and drug was sitagliptin. No serious ADRs documented and ADRs are predictable in nature. More precise side effects data on these drugs will help in reducing the ADRs burden and ascertain patient safety.

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