



Study of Adverse Drug Reactions Associated with Antiretroviral Agents At Government General Hospital & GMC, Anantapur

Authors

Dr. K. Santha Bai¹, Dr.P.Sreenivasulu Naik², Dr.N.M.Riyaz³, Dr.D.Kushbu⁴

¹Associate Professor, Dept. of Pharmacology,

²Dept. of STI, GGH, Anantapur

^{3,4}PG, Department of Pharmacology, GMC, ATP

ABSTRACT

Objectives: *To study the adverse drug reactions (ADRs) associated with antiretroviral agents (ARVs) in HIV positive patients.*

Methods: *The present study was a prospective observational study conducted at Government General Hospital, Anantapur from JUNE 2014 – JUNE 2015 (for one year period). Qualified Pharmacologist monitored all the in – patients receiving ARVs during the study period for suspected adverse reactions. WHO causality assessment scale, Modified Hartwig & Seigel scale and Modified Schumock & Thornton scales were applied to assess the causality, severity and preventability of the reported ADRs respectively. All cases and assessments were further reviewed by senior Pharmacologist & Head of the Department of STI.*

Results: *During the study period, 94 ADRs were observed in 71 patients. As per WHO scale, 80 ADRs were probable and 14 were possible. Based on the severity assessment, 10 ADRs were mild, 80 ADRs were moderate and 4 ADRs were severe in nature. Among the reported ADRs, 70 were definitely preventable and 24 were probably preventable. Antiretroviral drugs responsible for ADRs were Zidovudine (46), Stavudine (21), Nevirapine (10), Effavirenz (10), Lamivudine (5), Tenofovir (1), and Ritonavir (1). Among the reported ADRs, major ADRs were Anemia (25), Skin rashes (10), Hepatitis (10), Vomiting (10), Lactic acidosis (9), IRIS (5).*

Conclusion: *Regular monitoring of the HIV patients on ART is essential to identify and resolve ADR related morbidities.*

BACK GROUND AND SETTING

Among 2.3 million people living with HIV in India, around 0.3 million people are on government sponsored Anti-retroviral therapy.

HIV positive patients on ART may be hospitalized or any complication including Opportunistic Infections and are treated with multiple medications.

Morbidity associated with the ADRs in HIV positive local population is high with more than one third of the HIV positive patients treated with ART experiencing ADRs.

Increased access to ART in India needs monitoring of patients for ADRs to ART is must.

OBJECTIVES

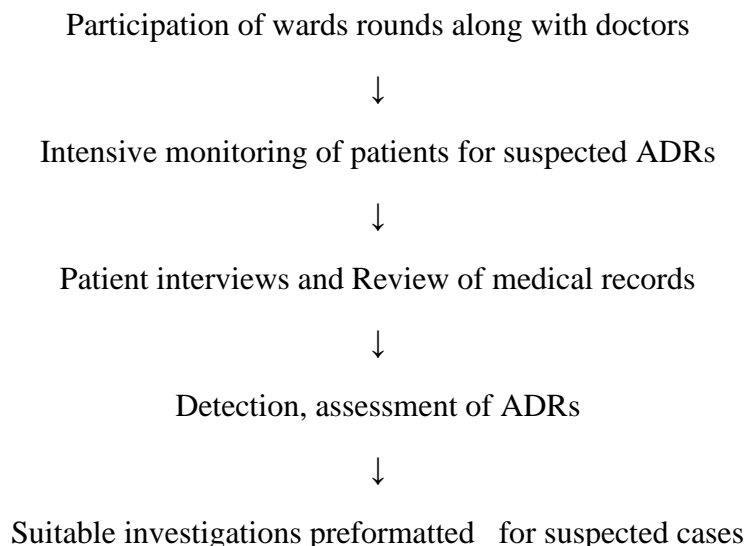
General objective:

To study the adverse drug reactions (ADRs) associated with antiretroviral agents (ARVs) in HIV positive patients.

Specific objective:

To assess the causality, preventability and severity of ARVs associated ADRs in hospitalized HIV positive patients.

METHODOLOGY



Adverse drug reactions

Causality	→	WHO causality Scale & Naranjo’s Scale
Severity	→	Modified Hartwig & Siegel scale
Preventability	→	Modified Shumock & Thornton Criterion

RESULTS

During the study period JUNE 2014-JUNE 2015 around one year period, 94 ADRs were detected in 71 patients.

Table.1 Demographic Details of study population

Demographics	No. Of patients	Percentage (N=71)
Gender		
Male	37	52%
Female	34	48%
Age (Years)		
1-18	4	5.6%
18-30	16	22.4%
30-50	44	62%
>50	7	10%

Table. 2 WHO Causality assessment

Category	No. of ADRS	Percentage (N=94ADRS)
Probable	80	85%
Possible	14	15%

Table 3 Severity Assessment

Levels	No. of ADRS	Percentage (N=94ADRS)
Mild		
Level 1	3	3.2%
Level 2	7	7.4%
Moderate		
Level 3	46	49%
Level 4(a)	20	21.2%
Level 4(b)	14	15%
Severs		
Level 5,6,7	4	4.2%

Table 4 Drug Combination implicated in ADRS

Drug Combination	No. of ADRS	Percentage (N=94ADRS)
Zidovudine+Lamivudine+Nevirapine	54	57.4%
Stavudine+Lamivudine+Nevirapine	21	22.3%
Zidovudine+Lamivudine+Efavirenz	15	16%
Stavudine+Lamivudine+Efavirenz	2	2.1%
Tenofovir+Lamivudine+Nevirapine	1	1.06%
Tenofovir+Lamivudine+Ritonavir+Atazanavir	1	1.06%

Table . 5 Suspected Drugs involved in ADRs with the Organ System Affected

WHO ART system organ class (soc code) ADRs	Drug(s) suspected ADRs	Number of ADRs and %(n=94)
1. Gastro-intestinasystem disorders(0600)		
Vomiting	AZT, d4t	10(10.6%)
Nausea	AZT	3(3.2%)
Diarrhea	3TC	2(2.1%)
Pancreatitis (Alkaline Phosphatase)	AZT	1(1%)
2. RBC disorders (1210)		
Anemia (Hemogram)	AZT	25(26.5%)

3.skin &appendages system disorder (0100)		
Rash (AEC count)	NVP, EFV	10(10.6%)
Pigmentation of nails	AZT	3(3.2%)
4. Liver and Biliary system disorders (0700)		
Hepatitis (L F T)	NVP, EFV	10(10.6%)
Lipodystrophy	d4T	4(4.2%)
Gynecomastia	RTV, EFV	2(2.1%)
Diabetes (Blood Sugar)	d4T	1(1%)
6. Resistance mechanism disorders (1830)		
IRIS	AZT+3TC+NVP, D4T+3TC+NVP, TDF+3TC+NVP	5(5.3%)
7. Central & peripheral nervous system disorders (0410)		
Peripheral neuropathy	d4T	4(4.2%)
Giddiness	, EFV	2(2.1%)
8. Body as a whole general disorders (1810)		
Headache	3tc	2(2.1%)

POLICY IMPLICATIONS AND CONCLUSION

- Close monitoring of patients started on ART for ADRs in the first SIX months is essential.
- Creation of registry for ADRs to ART, linking all ART centers across India would prove very useful.
- Regular monitoring of the HIV patients on ART is essential to identify and resolve ADR relate morbidities.

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