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A STUDY ON ADVERSE DRUG REACTIONS OF ANTI-RETROVIRAL THERAPY IN HIV POSITIVE PATIENTS IN A TERTIARY CARE HOSPITAL IN NORTH EAST PART OF INDIA

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ABSTRACT

Present study deals with Adverse Drug Reactions on Anti-Retroviral Therapy in HIV positive patients. Anti-Retroviral Drugs, no matter how safe and efficacious, are always coupled with inescapable risk of adverse reactions. Health care professionals should be alerted to assess adverse drug reactions after advising patients on which drugs to use. Present research work was a retrospective observational study carried out in Nodal ART center located in Guwahati Medical College Hospital, which is the largest and undoubtedly the most advanced tertiary care Govt. hospital of the entire north-east, catering to millions of people in this region. 575 HIV positive patients were enrolled into the study who were on ART. Majority of the population comprise of males and the significant association between incidence of Adverse Drug Reactions and various factors like Gender, mean CD4 cell count and BMI is evaluated using Fischer's exact test. Gastrointestinal system related ADRs were found to be the most prominent followed by CNS and skin related ADRs. Various drug regimens were checked for its toxicity potential and Zidovudine+ Lamivudine+ Efavirenz regimen was found to be most offending. Substitution of regimens due to toxicity was extensively studied. Causality assessment by Naranjo Scale, Severity assessment by Hartwig scale and Preventability assessment by Schumock and Thorntan ADR preventability scale were done for individual ADRs and majority of ADRs are found to be possible, mild and not preventable. As HIV/AIDS becomes a disease that can be both prevented and treated, attitudes will change, and denial, stigma and discrimination will rapidly be reduced.

KEYWORDS: Anti-retroviral therapy, adverse drug reactions, HIV, HAART.

INTRODUCTION

HIV does not kill anybody directly. Instead, it weakens the body's ability to fight disease. Infections which are rarely seen in those with normal immune systems are deadly to those with HIV. People with HIV can get many infections (called opportunistic infections, or OIs). Many of these illnesses are very serious, and they need to be treated. The introduction of highly active antiretroviral treatment (HAART) in 1996 radically changed the clinical course of human immunodeficiency virus (HIV) infection as it led to a dramatic reduction in mortality in these patients. However, these treatments have their limitations, including adverse effects, therapeutic failure, pharmacokinetic interactions, the development of resistance, and abnormal immune responses (Blanes M et al., 2009). Drugs, no matter how safe and efficacious, are always coupled with inescapable risk of adverse reactions. Early detection, evaluation and monitoring of ADRs are essential to reduce harm to patients and thus improve public health.

Antiretroviral drugs can cause side effects which are often mild, but sometimes they are more serious and can have a major impact on health or quality of life. On rare occasions, side effects can be life threatening. Side effects vary from person to person and it is impossible to predict exactly how everyone will be affected. Some people take antiretroviral treatment for years with few problems, while others find the same drugs intolerable. Health care professionals should be alerted to assess adverse drug reactions after advising patients on which drugs to use.

As HIV/AIDS becomes a disease that can be both prevented and treated, attitudes will change, and denial, stigma and discrimination will rapidly be reduced. This study is aimed at reporting the various ADRs related to Anti-retroviral use in ART Centre in GMCH and finding out the incidence, the offending drugs and types of such ADRs. This study is aimed at encouraging the health care professionals to provide better patient care by continuous monitoring of Anti-Retroviral therapy, reporting of unusual and known ADRs and effective management of such conditions.

MATERIALS AND METHODS

Study design: This was a Hospital based retrospective observational study.

Study location: The study was carried out in the ART center and inpatient Medicine departments of Guwahati medical college and hospital (GMCH), Assam. It is the largest and undoubtedly the most advanced tertiary care Govt hospital of the entire north-east, catering to millions of people in this region. With bed strength of nearly 1700, the Institution has 8 basic Science departments, 12 Clinical specialty and 11 Super specialty departments. In a year about 3.6 lakhs patients attend the OPD services and more than 50 thousand patients are admitted as in-patients in this hospital.

Study duration: The study was carried out over a period of 6-month duration.

Study criteria: Criteria for Identifying Adverse Drug Reactions - Spontaneous reporting of ADRs by practicing physicians in the ART center and in-patient departments of Medicine unit. Inclusion Criteria are Patients having at least one opportunistic infection who are eligible for ART according to NACO guidelines, Patients who had an ADR to ART being used for various indications, Patients of both sex and Patients of all ages. The prescriptions with incomplete information are excluded from the study. The study procedure involved use of some forms for data collection, documentation, causality assessment, severity assessment and analysis of the data.

Approval of the Institutional Human Ethics Committee and permission from the superintendent of Guwahati Medical College and Hospital were obtained prior to the study initiation. Personal meetings with the Head of the department (HOD), Professors and the practicing physicians in the ART Centre of the hospital were held, with a request to report the suspected cases of ADRs. All patients receiving ARTs for various indications in the department were screened for ADRs and only those patients showing ADRs and fulfilling the inclusion and exclusion criteria were included in the study. Their details were recorded in the case report forms. Study were based on those patients who experienced an ADR to ARTs use, either during their stay in hospital or those visiting the ART Centre and ultimately reported to the clinical pharmacist. For validation of ADRs all reactions were discussed and confirmed with the practicing physicians. All the data was represented as average and percentages.

Descriptive analysis was used for analysis.

RESULTS

In the present study, a total number of 575 patients were enrolled and followed up who are receiving Antiretroviral Therapy in ART Centre situated in Guwahati Medical College & Hospital. (Table 1)

Table 1: Basic demographics of study population.

Age	Number of patients	Percentage of patients
less than 15	21	3.65
15 to 30	110	19.13
30 to 45	401	69.74
Greater than 45	43	7.48
Gender		
Males	406	70.61
Females	169	29.39
Mode of transmission		
heterosexual	459	79.83
homosexual	8	1.39
BT	19	3.3
IDU	17	2.96
Perinatal	22	3.83
USI	3	0.52
Unknown	47	8.17

Incidence of adverse drug reactions

In the present study, out of 575, 197(34.26%) patients experienced ADRs. There occurred an ADR incidence of 68(24.2%) in 15-30 age group followed by 13(4.63%) in >45 age group. 4 patients (1.42%) in the age group below 15 experienced ADRs. The difference in the occurrence of ADRs in pediatric age group compared to adults was found to be significant ($p < 0.05$). Out of the 197 patients who experienced ADRs, 130 (65.99%) were males and 67 (34.01%) were females. The difference in the occurrence of ADRs in females compared to males was found to be significant ($p < 0.05$). Out of 575 patient population, 385(66.96%) did not experience any ADRs during Anti-Retroviral Therapy, whereas 116 (20.17%) patients experienced only 1 ADR. Rest of the 74 (12.87%) patients suffered with more than one ADR during their treatment. (Table 2)

Table 2: Incidence of ADRs.

Total number of patients	Number of patients with ADR	Percentage of patients with ADR
575	197	34.26%

Age group	Number of ADRs	Percentage of total number of ADRs
<15	4	1.42%
15 – 30	68	24.2%
30 – 45	196	69.75%
>45	13	4.63%

Sex	No. of patients with ADR	Percentage of patients with ADR
Male	120	64.17%
Female	67	35.83%
No of ADRs	**No. of patients experiencing ADRs**	**Percentage of patients**
0 (Patients with no Adverse drug reactions)	385	66.96%
1	116	20.17%
2	40	6.96%
3	24	4.17%
4	6	1.04%
5	1	0.17%
6	3	0.52%

In the present study, gastrointestinal system related ADRs constitute the major part, 140 cases which is 49.82% of total ADRs, followed by central nervous system related ADRs in 55(19.57%). Skin related ADRs were 31 (11.03%) followed by 29 (10.32%) Blood and CVS related ADRs. 10 patients (3.56%) experienced musculoskeletal system related ADRs. Lipid profile changes were observed in 6 patients (1.14%) as a result of drug therapy. Hepatic abnormalities and other ADRs were found in 5 (1.78%) each. (Table 3)

Table 3: Classification of ADRs according to organ system affected.

ADR classification according to system affected	No of cases	Percentage
Gastrointestinal system	140	49.82%
Central nervous system	55	19.57%
Skin	31	11.03%
Blood and cardiovascular system	29	10.32%
Musculoskeletal system	10	3.56%
Lipid profile changes	6	2.14%
Hepatic abnormalities	5	1.78%
Others	5	1.78%

Adverse drug reactions affecting gastrointestinal system

Gastritis constituted the most common GIT related ADRs with number of occurrences 67 (48.55%) followed by decreased appetite 27 (19.57%). Flatulence was observed in 12

patients (8.69%) whereas Anti-Retroviral treatment caused Nausea in 11 patients (7.97%) (Table 4).

Table 4: Adverse drug reactions affecting gastrointestinal system.

Adverse drug reaction	Number of patients	% of patients
Gastritis	67	48.55%
Decreased Appetite	27	19.57%
Flatulence	12	8.69%
Nausea	11	7.97%
Pain abdomen	9	6.52%
Epigastric tenderness	2	1.44%
Abdominal cramp	1	0.72%
Constipation	1	0.72%
Increased bowel movements	1	0.72%
Peptic ulcer	1	0.72%
Constipation	1	0.72%
Increased bowel movements	1	0.72%
Abdominal distension	2	1.44%
Gastro colic reflex	1	0.72%
Fullness of abdomen	1	0.72%

Adverse drug reactions affecting central nervous system

Decreased sleep was the most common CNS related ADR with number of occurrences 17 (34%) followed by giddiness 12 (24%). Headache was there in 8 (16%) patients followed by 2 cases (4%) of sleeplessness and neuropathy each. (Table 5)

Table 5: Adverse drug reactions affecting central nervous system.

Adverse drug reaction	Number of patients	Percentage of patients
Decreased sleep	17	34%
Giddiness	12	24%
Headache	8	16%
Sleeplessness	2	4%
Neuropathy	2	4%
Forgetfulness	1	2%
CNS problems	1	2%
Lethargy	1	2%
Tingling	1	2%
Increased sleep	1	2%
Disorientation	1	2%
Delusion	1	2%
Tremor of hands	1	2%
Malaise	1	2%

Adverse drug reactions affecting skin

Major skin related ADRs were rashes in 19 (61.29%) patients followed by Urticaria in 4 patients (12.9%). Steven-Johnson syndrome has occurred in 2 patients (6.45%). (Table 6)

Table 6: Adverse drug reactions affecting skin.

Adverse Drug Reaction	Number of Patients	% of Patients
Skin rashes	19	61.29%
Urticaria	4	12.90%
Steven-Johnson syndrome	2	6.45%
Photosensitivity reactions	1	3.23%
Hypersensitivity reactions	1	3.23%
Pyoderma of legs	1	3.23%
Tongue and buccal mucosa pigmentation	1	3.23%
Pigmentation of nails	1	3.23%
Angioedema	1	3.23%

Adverse drug reactions affecting musculoskeletal system

Paresthesia of legs and generalized weakness were the most common musculoskeletal system related ADRs which occurred in 2 patients (22.22%) each. (Table 7)

Table 7: Adverse drug reactions affecting musculoskeletal system.

Adverse Drug Reactions	Number of Patients	% of Patients
Paresthesia of legs	2	22.22%
Generalized weakness	2	22.22%
Shoulder ache	1	11.11%
Body ache	1	11.11%
Muscular pain	1	11.11%
Pain in loin	1	11.11%
Pain in hypochondrium	1	11.11%

Adverse drug reactions affecting liver

Out of the ADRs affected Liver, Increased liver enzyme levels were observed in 3 patients (37.5%) followed by lipodystrophy in 2 (25%). (Table 8)

Table 8: Adverse drug reactions affecting liver.

Adverse drug reactions	Number of patients	% of patients
Increased liver enzyme levels	3	37.5
Lipodystrophy	2	25
Swelling all over the body	1	12.5
Fatty liver	1	12.5
Leg swelling	1	12.5

Adverse drug reactions affecting Blood & CVS

Anemia was the most common Blood related ADR with number of occurrences of 20 (68.97%). Pallor occurred in 8 patients (27.59%) followed by palpitation in 1(3.45%) patients. (Table 9)

Table 9: Adverse drug reactions affecting Blood & CVS.

Adverse drug reactions	Number of patients	% of patients
Anaemia	20	68.97%
Pallor	8	27.59%
Palpitation	1	3.45%

Other adverse drug reactions

Lipid profile changes has occurred in 6 patients (50%) followed by difficulty in breathing, decreased vision, decreased hearing, increased frequency of micturition, burning feet and decreased weight with number of occurrences of 1 each (8.33%).

In the present study Stavudine +Lamivudine + Nevirapine combination is responsible for major number of ADRs 120 (42.7%) even though the same is considered as most common regimen, followed by Zidovudine +Lamivudine + Nevirapine which constitute nearly 86(30.60%) of total occurrence. Stavudine + Lamivudine + Efavirenz constituted 45 (16.01%) ADRs. Incidence rate of ZDV+3TC+EFV is found to be 39 (48.72%) followed by STV+3TC+NVP in 120 (30.61%) patients. Regimen with least incidence rate 45 (28.66%) was STV+3TC+EFV.

Initial Anti-Retroviral regimen in study population

Various regimens have been used which includes ZDV+3TC+EFV, ZDV+3TC+NVP, STV+3TC+NVP, STV+3TC+EFV, TDF+3TC+EFV, LPV/r+ABC+ddI and ZDV/TDF+3TC+LPV/r and the most used regimen is found to be STV+3TC+NVP (360, 62.61%), whereas LPV/r+ABC+ddI is found to be a very rare initial regimen used in 1 (0.17%) HIV positive patient. In the present study, 64(11.13) patients have received one substituted regimen in addition to their initial one due to ADR. (Table 10)

Table 10: Substitution of initial regimen with another.

Number of Substitutions due to toxicity	Number of patients whose regimens have substituted	Percentage
0	514	89.39%
1	56	9.74%
2	3	0.52%
3	2	0.35%

Substitution for stavudine toxicity

In the present study, substitution of Stavudine with Zidovudine due to Lipid profile changes was observed in 6 patients (46.15% of total Stavudine toxicity). Facial lipodystrophy, Neuropathy and Nausea caused substitution of Stavudine with Zidovudine in 2 patients (15.38%) each. Increased Liver enzyme level in 1 patient (7.6%) lead to substitution of Stavudine with Zidovudine. Substitution due to Stavudine toxicity is found to be 13 (19.12%) of total substitutions. (Table 11)

Table 11: Substitution for stavudine toxicity.

ADR	No. of substitution	Percentage (w.r.t. total no. of STV substitution)	Percentage (w.r.t. total substitution)	Nature of substitution
Lipid profile changes	6	46.15%	8.82%	Stavudine with zidovudine
Facial lipodystrophy	2	15.38%	2.94%	
Neuropathy	2	15.38%	2.94%	
Nausea	2	15.38%	2.94%	
Increased liver enzyme levels	1	7.69%	1.47%	
Total	13	100	19.12%	

Substitution for zidovudine toxicity

Anemia constituted the most important ADRs caused by Zidovudine which is substituted with Stavudine in 19 patients (51.35%) followed by Gastritis in 10 patients (27.03%). Decreased appetite increased liver enzyme levels and flatulence occurred in 2 patients each (5.41%) is substituted with Stavudine. Acute pancytopenia and Nausea and vomiting due to Zidovudine was substituted in 1 patient (2.70%) each. Substitution due to Zidovudine toxicity is found to be 37 (54.41%) of total substitutions. (Table 12)

Table 12: Substitution for zidovudine toxicity.

ADR	No. of substitution	Percentage (w.r.t. total no. of ZDV substitution)	Percentage (w.r.t. total substitution)	Nature of substitution
Anemia	19	51.35%	27.94%	**Zidovudine with stavudine**
Gastritis	10	27.03%	14.71%	
Decreased appetite	2	5.41%	2.94%	
Increased liver enzyme levels	2	5.41%	2.94%	
Flatulence	2	5.41%	2.94%	
Nausea and vomiting	1	2.70%	1.47%	
Acute pancytopenia	1	2.70%	1.47%	
Total	37	100	54.41%	

Substitution for nevirapine toxicity

In the present study, Maculopapular rashes due to Nevirapine occurred in 12 patients (80%) who have undergone substitution of Nevirapine with Efavirenz. Because of Steven-Johnson syndrome due to Nevirapine 2 patients (13.33%) were substituted with Efavirenz. Hypersensitivity reactions caused substitution with Efavirenz in 1 patient (6.67%). Substitution due to Nevirapine toxicity is found to be 15 (22.06%) of total substitutions. (Table 13)

Table 13: Substitution for nevirapine toxicity.

ADR	no. of substitutions	Percentage (w.r.t. total no. of NVP substitution)	Percentage (w.r.t. total substitution)	Nature of substitution
Maculopapular rashes	12	80%	17.65%	Nevirapine with Efavirenz
Steven-Johnson Syndrome	2	13.33%	2.94%	
Hypersensitivity reactions	1	6.67%	1.47%	
Total	15	100	22.06%	

Substitution for efavirenz toxicity

Insomnia, Paresthesia and CNS problems associated with Efavirenz therapy caused substitution in 1 patient each (33.33%) with Nevirapine. Substitution due to Efavirenz toxicity is found to be 3 (4.41%) of total substitutions. (Table 14)

Table 14: Substitution for efavirenz toxicity.

ADR	no. of substitution	Percentage (w.r.t. total no. of EFV substitution)	Percentage (w.r.t. total substitution)	Nature of substitution
Insomnia	1	33.33%	1.47%	Efavirenz with Nevirapine
Paresthesia	1	33.33%	1.47%	
CNS problems	1	33.33%	1.47%	
Total	3	100%	4.41%	

Assessment of Severity, Causality and Preventability of adverse drug reactions

Out of the 281 ADRs, 179 (63.70%) ADRs were found to be "possible" while the 102 (36.29%) were classified as "probable". (table 15)

Table 15: Causality assessment by naranjo scale.

Causality	Score	No of ADRs (%)	% of ADRs
Definite/highly probable/certain	9	0	0
Probable	5-8	102	36.29
Possible	1-4	179	63.70
Unlikely	0	0	0

Severity assessment by hartwig scale

Most of the ADRs 190 (67.62%) was classified as "mild" and 61 (21.71%) as "moderate". Only few ADRs were found to be "severe" 30 (10.68 %). (Table 16)

Table 16: Severity assessment by hartwig scale.

Severity	Score	No. of ADRs
Mild	Level 1 & Level 2	190 (67.62 %)
Moderate	Level 3 & Level 4	61 (21.71%)
Severe	Level 5 & Level 6	30(10.68%)

Preventability assessment by Schumock and Thorntan ADR preventability scale

Out of 281 ADRs only 8(2.85%) were found to be preventable. (Table 17)

Table 17: Preventability assessment by Schumock and Thorntan ADR preventability scale.

Preventability	No. of ADRs	% of ADRs
Preventable	8	2.85%

DISCUSSION

Strength of the study include the recruitment of 575 patients who were started therapy from March 2005 to January 2011 and the information from the case reports maintained properly

in ART Centre, Guwahati as well as by spontaneous reporting by practicing physicians. Most of the patients belong to the age category 30-45 years with a mean age of 34.38+_9.26 years. This is comparable to the previous study by Manosuthi et al., (2007) where the mean age was 35.2+_7.4 years. The male: female ratio was 2.4:1. This is more or less similar to other studies carried out in Southern part of India (Rajesh et al., 2011).

In our study, the overall incidence of ADR to highly active antiretroviral therapy was found to be 34.26%. Incidence is found to be lesser than earlier studies (Rajesh et al., 2011) where it was 43.85%. This may be because of the concurrent medications used for treating Opportunistic infections observed in previous studies. Of the 197 suspected ADR patients 115(61.49%) developed one ADR, 39(20.85%) developed two ADRs, 23 patients (12.29%) developed three ADRs, 6(3.05%) patients developed four ADRs, 1(0.507%) developed five ADRs and 3(1.522%) developed six ADRs. Above mentioned results in the present study differs significantly from the other studies where incidence of more than 4 ADRs in one patient is not accounted in any of the previous studies (Rajesh et al., 2011). This may be due to the longer duration of follow up and higher number of patients in the present study.

Present study details the distribution of ADRs in different age group of patients. Maximum number of ADRs was found in 30-45 years age group 196 (69.75%). This result is not similar to the studies in other parts of India (Rajesh et al., 2011) which explain the higher incidence rate of ADRs in >60 age group. In the present study, only 3 patients belong to the group >60 years and out of them only 1 experienced the ADR. So extended study of patients who belong to >60 years age is needed to explain the difference in incidence rate.

The prevalence of ADRs in our study was higher in females [39.41% (67/169) compared to male population 29.56% (120/406) and this difference was significant. ($p<0.05$). This finding is supported by a previous prospective, observational cohort study (Singh et al., 2009) where female patients had more ADRs (45.71%) compared to males (11.36%). Higher incidence rate of different ADRs due to different drugs in women were reported by Hassan SS et al., in 2011, Muurahinen et al., in 1999, Gatti et al., in 1999, Lucas et al., in 1999 and Currier et al., in 2000. The reasons for these sex differences in adverse drug events are not firmly established but the possible causes might be differences between men and women in body mass index and fat composition, hormonal effects on drug metabolism, or genetic constitutional differences on the levels of various enzymes.

Among the organ systems affected by ADRs, GIT is affected most predominantly that is 140 cases (49.82%) of total ADR. This is comparable to previous studies (Khalili et al., 2009) where GI toxicity was most prominent with incidence rate 63.7%. This was followed by CNS with incidence rate 19.573%. Skin and hematological toxicity were 11.03% and 10.32% respectively. These results are comparable to previous studies done in other parts of India (Singh et al., 2009) which found out skin related toxicity incidence rate as 15.83%. However, study done by Rajesh et al., 2011 reported higher incidence of hematological toxicities.

Most frequently used regimen was STV+3TC+NVP 46.45%, followed by ZDV+3TC+NVP 33.63%, STV+3TC+EFV 18.5% patients and the least used regimen was TDF+3TC+EFV used by 1.2% followed by LPN/r+ABC+ddI by 0.001% (For both initial and substituted regimen). While analyzing the ADR data of various regimens with respect to number of patients receiving it, the most toxic regimen found was ZDV+3TC+EFV (incidence rate of 48.72%), followed by STV+3TC+EFV (28.66%). This is not comparable to the previous study (Rajesh et al., 2011) who found out the regime having maximum incidence rate as ZDV+3TC+NVP. This can be explained by increased number of patients enrolled in the study and longer duration of follow up in present study.

Zidovudine was mainly responsible for Anemia, Gastritis and Decreased appetite whereas Stavudine was responsible for Neuropathy, Facial lipodystrophy and Forgetfulness. Nevirapine mainly accounts for Steven-Johnson Syndrome being the most severe medical emergency along with Maculopapular rashes. Efavirenz was mainly responsible for CNS problems, sever attack of giddiness, delusion and decreased orientation and Tenofovir was responsible for giddiness and headache. This finding can be supported by evidences documented in previous study (Subbaraman et al., 2007).

Drug reactions leads to substitution of existing regimens were studied. 56 patients have undergone one substitution while 3 people changed their ART regimens twice according to physician’s advice. 2 patients substituted their regimens 3 times because of toxicity. Substitution due to Zidovudine toxicity accounts for 37 (54.41%) of total substitution. This finding is similar to previous studies (Kumarasamy et al., 2009) where the substitution of Zidovudine with Stavudine had happened in half of the population. Stavudine toxicity accounts for 13(19.12%) of total substitutions. These results are not similar to earlier studies in Uganda which found out 84% of substitutions because of Stavudine. Substitution due to Nevirapine toxicity accounts for 30(7.65%) of total substitution which is comparable with

previous studies (Griensvena et al., 2010) where the percentage of substitution was 6.2%. substitution because of Efavirenz therapy in the present study was 19 (10.5%) which is similar to the previous study (Schouten et al., 2010). Difference in the findings related with Stavudine toxicity in previous studies may be because their study was limited to only the population on regimens containing Stavudine therapy.

Final purpose of the present study was to assess the severity, causality and preventability of ADRs occurred in the study population. Causality assessment using Naranjo scale showed a total number of 179 (63.70%) of reactions were "Possible" with causality score 1-4, followed by 102 (36.29%) ADRs those are "Probable". These results are not matching with previous studies done where majority of reactions 47(63.5%) were Probable and 26 (35.2%) were Possible (Rajesh et al., 2011).

Assessment of severity using Hartwig scale clearly gave a picture that 30 (10.68%) of total ADRs "Severely" affected the patients while majority (67.62%) of toxic reactions were mild which is supported by already existing studies (Zuk et al., 2009). This may be due to the shorter exposure time of the patient to offending drug or due to apt substitution with another drug/ regimen on time. Preventability assessment revealed that out of 281 ADRs, 8 were preventable if adequate care might have taken. Preventability was very less (2.85%) which is supported by study which revealed the ADRs are less likely to be preventable in HIV-infected patients than in those with negative or unknown HIV status (Mehta et al., 2007). However, the severity and preventability were different from the study done by Rajesh et al., 2011. This difference may be due to larger population taken up and longer duration of present study.

CONCLUSION

Incidences of ADRs were significantly higher in Females. Gastrointestinal system involvement was the commonest ADR encountered. Zidovudine + Lamivudine + Efavirenz was responsible for majority of ADRs. Majority of the ADRs were possible, mild and not preventable. However, prospective study taking a larger sample is necessary to arrive at a definite conclusion.

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