IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
July 2016 Vol.:6, Issue:4

A Study of Drug Utilization Pattern and Assessment of Quality of Life in HIV Infected Patients

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ISSN 2349-7203
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Submission: 30 June 2016
Accepted: 5 July 2016
Published: 25 July 2016

Keywords: Drug utilization pattern; Quality of life; Human immunodeficiency virus (HIV); ART/HAART

ABSTRACT

The hospital based study was carried out to study the drug utilization pattern, co- morbidities associated with HIV, to identify drug related problems with ART (anti-retroviral therapy) and to describe the quality of life of patients living with HIV. Among the 103 selected patients, Out of the 103 patients who enrolled 73 (70.8%) were male and 30(29.1%) were female, the maximum number of patients affected with HIV found were in the age group of 31-45 years. The patients were prescribed with ART with different combination of HAART, the most often prescribed was Zidovudine (300mg) + Lamivudine (150mg) + Nevirapine(200mg) in 34 patients, followed by Tenofovir (300mg) + Lamivudine (150mg) + Efavirenz(600mg) combination in 12 patients. The type of ADRs encountered were anemia, rashes, nausea/vomiting, headache, diarrhea and fever.The co-morbidities associated with HIV were 27; the most common one was TB (30.09%), followed by acute GE (18.4%). The different drug related problems were drug-drug interactions (213), drug-food interactions were 10 and adverse reactions were 22. According to the modified WHO QOL BRIEF 5 point Likert scale,the maximum number of HIV patients has shown low Quality of life in all the Domains 1 to 4. Low score in any one domain can affect the overall quality of life of a HIV patient. The result of the study suggest that the prescribing pattern was in accordance with national guidelines, but still, there is a scope for improvement by using the viral load as a biomarker instead of CD4.There is a tremendous scope for clinical pharmacist in creating an awareness of HIV among community, improvement of patient's quality of life by enhancing the medication adherence of ART and minimizing the drug related problems in cooperation with other health care professionals.

INTRODUCTION

HIV stands for Human Immunodeficiency Virus; it infects the certain types of white blood cells, principally CD4 cells and monocytes/macrophages. CD4 cells and macrophages play an important role in immune system of a body. The disruption of functions of these cells lies at the heart of the immunodeficiency that characterizes AIDS.

A weakened immune system offers the development of secondary infections such as tuberculosis and others diseases. HIV can cause severe weight loss due to damage to the lining of the intestine and damages the nerve cells causes, neurological problems. [1, 2, 3]

AIDS is the acronym for "Acquired Immune-Deficiency Syndrome" which is a fatal disease in which CD4 cells drop below 200 cells/mm3 of blood. Its exponential progression and tremendous impact on mankind are still frightening. AIDS emerged as one of the most important public health issues of the late twentieth and early twenty- first centuries and is now one of the leading causes of global morbidity and mortality.[4]

Over the past decade, the HIV/AIDS epidemic in India has grown from a handful of HIV infected persons to a major public health problem with tremendously growing medical psychosocial and economic consequences for the country.

The infection initially spreads among commercial sex workers and intravenous drug users. It then swiftly spreads from high risk group to their partners/clients, and subsequently to the spouse and finally to their children. Heterosexual transmission remains the most frequent mode of transmission, followed by blood transfusion, intravenous drug users and perinatal.[5]

At the present time, the goal of treatment is to halt or at least significantly slow the progression of the diseases. If the virus can be controlled with antiretroviral drugs, the immune system can function competently and no opportunistic infections will develop. This is the purpose of antiretroviral treatment. The development of antiretroviral therapy has been one of the most dramatic evolutions in the history of medicine as of now there are 30 individual or combination agents licensed for treatment of HIV infection.[6]Effective treatment slows or stops the progression of HIV disease to AIDS and, for most people, seems likely to extend healthy life indefinitely.[7]

According to the HIV Estimations 2012, the estimated number of people living with HIV/AIDS in India was 20.89 lakhs. HIV prevalence at national level has continued its steady decline from estimated level of 0.41% in 2001 to 0.27% in 2011. But still, India is determined to have the third highest number of estimated people living with HIV/AIDS, after South Africa and Nigeria (UNAIDS Report on the Global AIDS epidemic 2010). The Millennium Development Goals (MDGs) commit all countries to reverse the spread of HIV/AIDS by 2015.

As a signatory nation, India stands committed to achieve this goal through its National AIDS Control Program (NACP) which provides a comprehensive prevention, care and treatment program with standardized ART regimens at free of cost with a robust monitoring and evaluation system through various ART centers. [8]

The study was subjected to determine the drug utilization pattern, medication adherence and opportunistic infections among HIV positive patients attending ART (Anti-Retroviral Therapy) Centre of a tertiary care hospital. Drug Utilization Evaluations (DUE) or Medication Utilization Evaluations (MUE)is an authorized, structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication. DUEs involve a comprehensive review of patients' prescription and medication data before, during, and after dispensing to ensure appropriate medication decision making and positive patient outcomes.The data thus obtained would give feedback to clinicians and the health care decision makers regarding compliance of the treatment offered with regard to the standard guidelines and thus promoting rational drug use.[9]

Strict adherence to antiretroviral therapy (ART) is the key to sustained HIV suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, [10, 11] as well as decreased risk of HIV transmission. Poor adherence to an HIV regimen allows HIV to destroy the immune system. A damaged immune system makes it hard for the body to fight off infections and certain cancers. Poor adherence also increases the risk of drug resistance and HIV treatment failure.[12]

ARV drugs have revolutionized the treatment for HIV by increasing the average lifespan of HIV-positive individual. QOL of PLHIV has become a salient issue after the increase in availability of ARV and increase in average life span. WHO defines QOL as individuals' perceptions of their

position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.[13] QOL is identified as a useful medium to measure or determine the efficacy of treatment or interventions. [14] Therefore, the present study was conducted to investigate the QOL of Indian PLHIV receiving ART and examines the factors that may affect it.

WHOQOL-HIV BRIEF version [11] was used to investigate the QOL of PLHIV receiving ART. The scale produces six domain scores namely physical, psychological, level of independence, social relationships, environmental, and spirituality, religion, personal beliefs (SRPB). Individual items are rated on a 5-point Likert scale where 1 indicates low, negative perceptions and 5 indicate high, positive perceptions. Higher score indicates better QOL.[15]

MATERIALS AND METHODS

Study design and setting: A prospective observational study was conducted for a period of six months in the department of Medicine, Shri B. M. Patil Medical College Hospital and Research Center after obtaining the Institutional Ethical Committee clearance. Hospital provides primary and specialized health care facilities to people in and around Vijaypur district. The patients admitted to the general medicine ward were screened according to inclusion and exclusion criteria and 103 patients were selected for the study.

Inclusion criteria:

- In patients of either gender with HIV or HIV with different opportunistic infection admitted to medicine ward of a tertiary care hospital.
- Adult age >14 years.

Exclusion criteria:

- All the outpatients.
- Inpatients below the age of 14 years.
- Inpatients excluding medicine department.
- Pregnant and lactating women.

Source of data: Patient case file consisting of demographic and medication details, patient interview, Truven Micromedex online database and Stockley's Drug-Drug Interactions textbook.

Data collection:

Data from each patient was collected by either interview or patient case file or both of the above. The collected data from each Patient was documented and evaluated for study parameters. For the drug-drug interactions assessment, the Micromedex online database and Stockley's Drug-Drug Interactions textbook was utilized.

RESULTS

The selected 103 patients were divided gender wise, in which males were 73 (70.8%) and females were 30 (29.1%) (Table 1).

The maximum (62) number of patients affected with HIV were in the age group of 31-45 years (60.1%) followed by 15-30 years (20) (19.4%), followed by age group of 46-60 years comprising of 17 (16.5%) with least percent of age group being 61-75 years comprising of about 3.83% (Table 2)**.** The duration since patient diagnosed with HIV positive was classified into ≤1 year having 25.2% of the patients followed by >1 to <5 years with 52.4% followed by >5 years consisting of 22.3% of the patients. The majority of the patients diagnosed were in >1 year-<5 years with 52.4% (Table 3).

Around 1008 drugs were used in 103 patients, among 655(64.9%) were per oral administrations, 302(29.9%) were injectable, 24(2.3%) were topical and 27(2.6%) were inhalers. The majority of drugs prescribed were oral route followed by parental and topical (Table 4).

The patients receiving ART regimen with different combination of HAART were Zidovudine (300mg) + Lamivudine (150mg) + Nevirapine (200mg) in 34 patients, whereas Tenofovir (300mg) + Lamivudine (150mg) + Efavirenz (600mg) was given to the 12 patients, then it is followed with a combination of Efavirenz (600mg) + Lamivudine (150mg) + Zidovudine (300mg) to 10 number of patients and very few patients (8) were prescribed with the combination of Tenofovir (300mg) + Emtricitabine+ Efavirenz (600mg) (Table 5)**.**

The different class of drugs were prescribed for patients in which, 268 antibiotics, 53 antifungals, 15 antimalarial, 18 antiprotozoal, 16 antivirals, 27 anti-diarrhoeals, 30 iron supplement, 25

vitamins, 32 steroids, 23 diuretics, 102 anti-ulcerative, 24 anti-emetics, 67 respiratory, 23 ant-hypertensive, 180 anti-tubercular agents, 52 paracetamol. Out of 1008 prescribed for 103 patients 209 were prescribed for prophylaxis usage 67 cotrimoxazole, 18 azoles, 43 cephalosporin, 28 quinolones, 53 antifungals (Table 6).

The total number of co-morbidities associated with HIV were 27, most common co-morbid was TB (30.09%), followed by acute GE (18.4%), LRTI (7.7%), meningitis (6.79%), UTI (5.82%), oral candidiasis 5.82%, clinical malaria (4.85%), HBV (1.94%), others (46.6%) (Figure 1).

255 drug related problems were observed. Among these 255 problems, (83.5%)were drug-drug interactions followed by (3.92%) drug-food interaction, (8.62 %) adverse drug reactions and others 10 (3.92%). (Table 7). The various adverse reactions were anemia (36.30%), diarrhea (18.18%), N/V (13.63%), headache (13.63%), and least rashes and fever (9.09%). (Figure 2) The total drug –drug interactions were 213 among them major was 67(31.4%) followed by moderate 114 (53.5%) and minor was 32 (15.0%). (Table 8). The drug interactions with HAART regimen in the patients receiving HAART were 73. (Table 9).

HIV/AIDS is known to affect an individual's physical health, mental health, social relationships and financial status of patients. According to the modified WHO QOL BRIEF 5 point Likert scale 66.9% (69) of the patients were having low quality of life in domain 1 (physical health), followed by 48.5% (50) were in domain 2 (psychological), followed by 63.1%(65) in domain 4 (environment). Whereas in domain 3 (social relationship) majorities of patients have shown average quality of life 57.2% (59). Low score in any one domain can affect the overall quality of life of patient hence the majority of patients enrolled in the study were having low quality of life in relation to physical health, psychological and environmental aspects (Figure 3).

Out of 103 patients enrolled in the study, majority of patients 62.1% (64) were low adherent to their medication, followed by 33.0% (34) who were medium adherent and only small group of people 4.85% (5) were high adherent to their medication (Figure 4). Non-adherence to treatment and treatment failure is associated with an increased risk of uncontrolled HIV infection**.**

DISCUSSION

In the present study, the number of male patients were more compared to females and majority were belongs to middle aged groups. This distribution of gender and age group is in contrast with similar study conducted by Chackojiyo *et.al*on DUP of ART in HIV positive patients.[16]

Majority of patients received HAART with oral route of drug administration followed with parenteral wherever is necessary, indicates the oral is most accepted and compatible with patients, these type of results were comparable with previous study conducted by Kapadia, *et al*.[17]

The patients who have received different ART therapy combination in the present study were comparable to study conducted by Chackojiyo *et al*., indicates the medical practitioners practices the fixed drug combination for the treatment of HIV/AIDS.[16]

Polypharmacy play an important role in combating the HIV, hence different classes of drugs are necessary along with NRTIs (nucleoside reverse transcriptase inhibitors) and NNRTs (non-nucleoside reverse transcriptase inhibitors). The most commonly prescribed class was antibiotics, followed by iron supplements and vitamins. The other classes of drugs used were antacids, anti-emetics, bronchodilators, anti-hypertensive and NSAIDs(Paracetamol). This is similar to the study conducted by Chackojiyo *et.al*where antibacterial agents were the second most common class of drugs prescribed and the most common antibacterial agent used was cotrimoxazole. The increased use of cotrimoxazole is justifiable as it is recommended for chemoprophylaxis against Pnemocystis carni Pneumonia.[16]

Tuberculosis was found to be most common opportunistic infection (OI) encountered in HIV in the present study, which is similar to the study conducted byKapadia, *et al*., the nest co-morbidity found was acute gastroenteritis and followed with others diseases, hence it justifies the use of polypharmacy and different class of drugs. [17]

The risk for drug–drug interactions may be particularly increased among the population of HIV-infected adults due to treatments for multiple comorbidities in this population as well as the concomitant use of ARV therapy. We found that 73 number of daily non-ARV medication can also increase the risk of ARV/non-ARV combinations which were potential for clinically

significant interactions with HIV infected persons. This is in accordance with the study conducted by the Carol Holtzman, PharmD Polypharmacy and Risk of Antiretroviral Drug Interactions Among the Aging HIV-Infected Population.[18]

Adverse drug reactions (ADRs) were common with ART and other drugs, as immune system is decreased in HIV. Among 103 enrolled patients 22 were reported with ADRs with ART drugs. The most commonADRs occurred were anemia, diarrhea, nausea &vomiting, headache and least founded ADRs were rashes and fever which are in contrast with the study conducted by Ajay Sharma *et.al*, in which more ADRs were observed and many cases had ≥ 1 ADRs. The most common ADRs found with Ajay Sharma *et. al*. were cutaneous nail hyperpigmentation and rash. Rash was mainly observed with nevirapine based regimens and in one case with efavirenz (EFV)-based regimen, these kind of ADRs were not seen with present study.[19]

According to the modified WHO QOL BRIEF 5 point Likert scale majority of patients were having low quality of life in physical health domain and in environment domain and about a half were having low QOL in psychological domain and few in social relationship domain.This data reveals that the majority of the patients were with low quality of life in all domains, this statement is in accordance with the study conducted by Imam H *et.al*whereHIV-infected people from three NGOs and one Infectious Disease Hospital (IDH), were interviewed using an interviewer administered, semi-structured questionnaire developed by adopting the "WHOQOL-HIV BRIEF instrument". A majority of the respondents were with low Quality of Life (QOL) in all the domains. This low quality of life may be due to poor medication adherence, low economic status and others. [20]

In the present study, the proportion of patient with low QOL (Quality of life) was highest in physical health domain(Domain 1) which was in contrast with the study conducted by Imam H *et.al*. The proportion of respondents with low QOL was highest in the domain of social relationship.

The variation in these two studies is due to the presence of concomitant diseases along with HIV was high in patients enrolled in our study which greatly affect the overall physical heath of the patient. The second highest domain reflects the low quality of life was environment this suggest that the patient didn't have better quality of health services and accessibility which was found to

be in contrast with the study conducted by Imam H *et.al*. in which the second most was psychological domain.[20]

As concerned with the medication adherence (62.1%) patients were low adherent to their medication followed by (33.0%) medium adherent and least (4.85%) high adherent to their medication. This is similar to the study conducted by Jorge Enrique machando alba *et.al*. in which the study population was composed of 510 HIV-positive patients undergoing antiretroviral treatment report of noncompliance were found in 198 treatment cases (38.8% of patients); these patients notified the attending physician that they were not taking the therapy for a variety of reasons (e.g., lack of adherence and ignorance).[21]

Non-adherence to treatment, treatment failure, the presence of anxiety or depression, were associated with an increased risk of uncontrolled HIV infection.

CONCLUSION

India is the third largest country in the world as concern with HIV prevalence, basically, it is important to bring awareness among the community regarding transmission and development of HIV to AIDS, especially in rural areas.

In the present study, it is tried to explore the different age group of people suffering from HIV and the ratio of male and female patients affecting with HIV. Early diagnosis plays an important role to start the HAART therapy in order to stop the further progression of the disease. The prescribing pattern of drugs for HIV patients were with HAART therapy, along with other polypharmacy in order to improve the immune system, which is important in HIV.As HIV most of the times co-morbid with other opportunistic infections. As the immune system is decreased in HIV, susceptibility of ADRs is increased with ART drugs, hence careful monitoring is required in order to reduce the severity of ADRs with help of clinical pharmacist and other health care providers. The role of clinical pharmacist is more emphasized in ordering the prescribing pattern of drugs, reducing the ADRs and enhances the medication adherence, which improves the quality of life of a patient.

ACKNOWLEDGEMENT

Authors are thankful to Principal and staff of BLDEA's College of Pharmacy and Shri. B M. Patil medical college hospital and research centre for providing the necessary facilities and timely support in order to complete the research work.

CONFLICT OF INTEREST

Authors do not have any conflict of interest

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Table 1: Gender wise categorization of patients suffering from HIV

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Gender	No. of patients	Percentage
Male	73	70.8%
Female	30	29.1%

Table 2: Distribution of age groups of patients living with HIV

Age groups	No. of patients	Percentage
15-30	20	19.4%
31-45	62	60.1%
46-60	17	16.5%
61-75	4	3.83%

Table 3: Categorization of patient according to the duration since they diagnosed

Years	No. of patients	Percentage
≤1year	26	25.2%
>1year to<5year	54	52.4%
>5year	23	23.3%

Table 4: Classifications of dosage forms

Dosage forms	No. of drugs	Percentage
Injectable	302	29.9%
Oral	655	64.9%
Inhalers	27	2.6%
Topical	24	2.3%

Table 5: Most frequently prescribed HAART combinations

S.No	Combination	No. Of Patient	Percentage
1.	Zidovudine (300mg)+ Lamivudine (150mg) + Nevirapine(200mg)	34	47.2%
2.	Tenofovir (300mg) + Lamivudine (150mg) + Efavirenz(600mg)	12	16.6%
3.	Efavirenz(600mg)+Lamivudine(150mg) + Zidovudine (300mg)	10	13.8%
4.	Tenofovir (300mg) +Emtricitabine+ Efavirenz(600mg)	08	11.1%
5.	Others	08	11.1%

Table 6: Polypharmacy in HIV Positive Patients

S.no	Drugs	No. of drugs	Percentage
1.	**Antibiotics**	**184**	**18.34%**
	Clotrimoxazole	67	6.64%
	Cephalosporins	43	4.26%
	Quinolones	28	2.7%

	Azithromycin	25	2.48%
	Amoxycillin+clavulanic acid	21	2.08%
2.	**ATT**	**180**	**17.85%**
	Isoniazid	45	4.46%
	Rifampicin	45	4.46%
	Pyrazinamide	45	4.46%
	Ethambutol	45	4.46%
3	**Antifungals**	53	5.25%
	Fluconazole	53	5.25%
4	**ART**	319	31.80%
	NRTI'S	187	58.62%
	Zidovudine	36	3.5%
	Stavudine	8	0.79%
	Lamivudine	61	6.05%
	Tenofovir	82	2.70%
	NNRTI'S	132	13.1%
	Nevirapine	39	3.86%
	Efavirenz	93	9.22%
5	**Other viral drugs**		
	Acyclovir	16	1.56%
6	**Antiprotozoal**		
	Metronidazole	18	1.78%
7	**Iron supplements**	30	2.97%
8	**Vitamin supplements**	25	2.48%
9	**Respiratory disorders**	67	2.67%
10	**Anti –ulcers drugs**	102	10.11%
11	**Anti-emetics**	24	2.38%
12	**Anti-hypertensives**	23	2.25%
13.	**NSAID'S**	52	5.15%

Table 7: Total number of drug related problems

SI.no	Drug related problem	Frequency	Percentage
1.	Drug-drug interaction	213	83.5%
2.	Drug –food interaction	10	3.92%
3.	Adverse drug reactions	22	8.62%
4.	Others	10	3.92%

Table 8: Severity of interaction

Severity	Frequency	percentage
Major	67	31.4%
Moderate	114	53.5%
Minor	32	15.0%

Table 9: Drug interaction with HAART regimen

s.no	ART+other drugs	Frequency	percentage
1.	Lamivudine+SMX/TMP	18	24.65%
2.	Efavirenz+rifampin	12	16.43%
3.	Nevirapine+rifampin	2	2.73%
4.	Zidovudine+pyrazinamide	8	10.95%
5.	Nevirapine+amlodipine	3	4.10%
6.	Zidovudine+SMX/TMP	5	6.84%
7.	Zidovudine+rifampin	2	2.73%
8.	Tenofovir+ranitidine	2	2.73%
9.	Efavirenz+dexamethasone	2	2.73%
10.	Zidovudine +acetaminophen	8	10.95%
11.	Nevirapine+fluconazole	6	8.21%
12.	Dexamethasone+nevirapine	5	6.84%

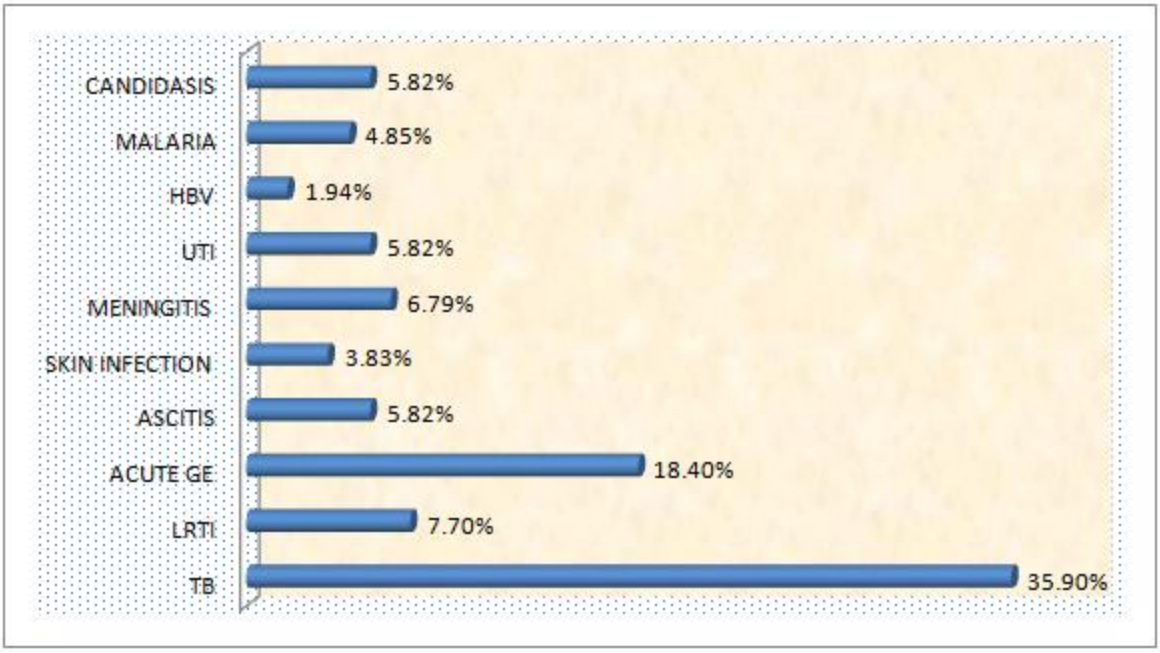

Figure 1: Co-morbidities with HIV positive patients

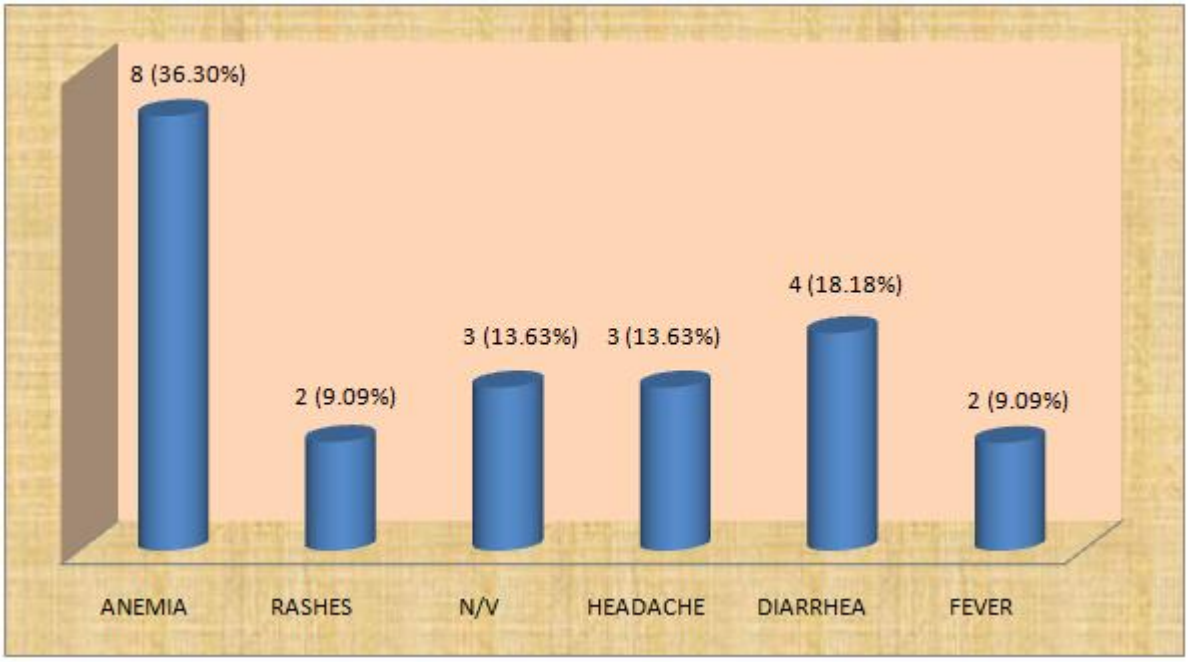

Figure 2: Adverse drug reactions observed in the study.

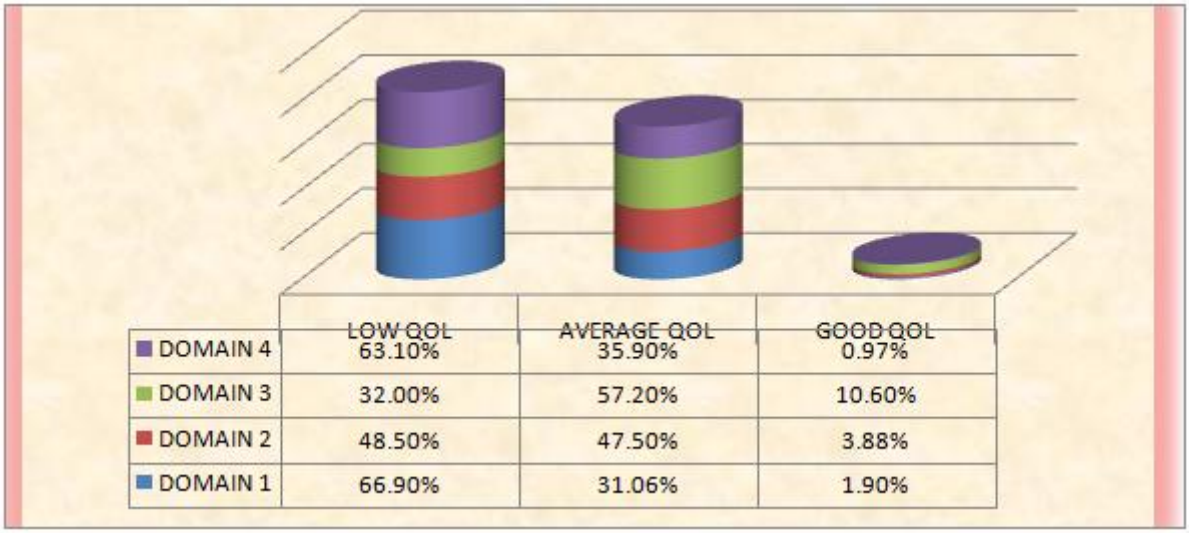

Figure 3: Assessment of Quality of life with HIV patients.

Keys: DOMAIN 1: Physical health; DOMAIN 2: Psychological; DOMAIN 3: Social relationship; DOMAIN 4: Environment health. QOL: Quality of Life.

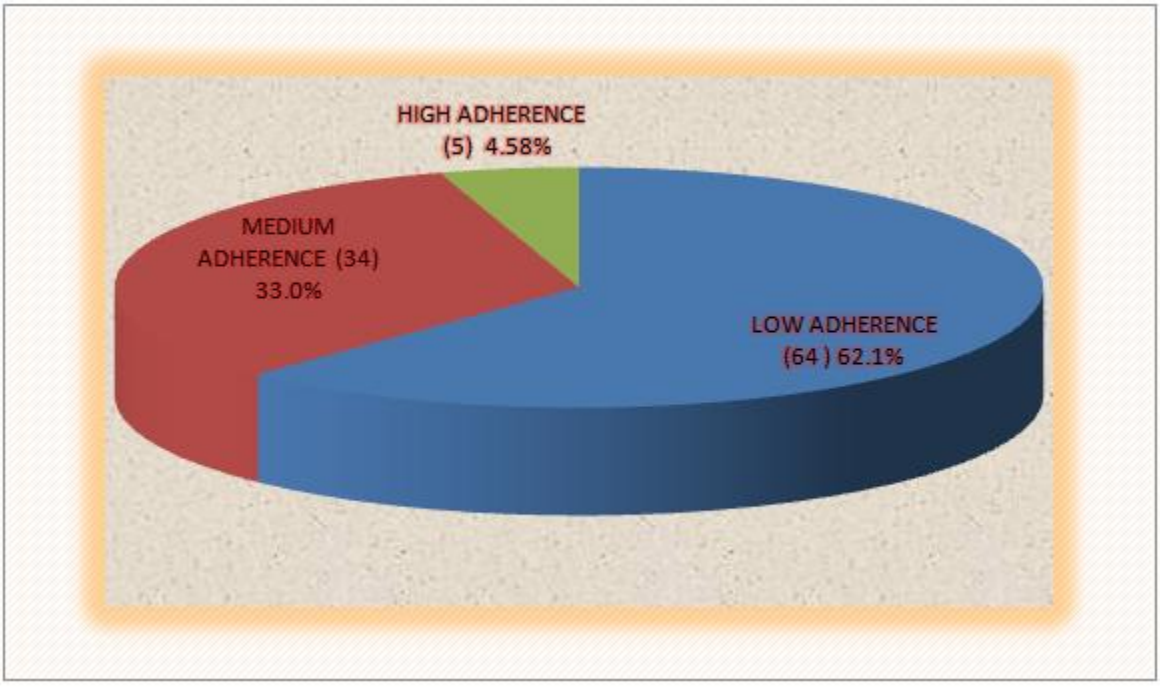

Figure 4: Medication adherence