

# Drug utilization study of HIV positive patients registered with antiretroviral therapy centre of a tertiary care hospital

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## ABSTRACT

**Objective:** To determine the drug utilization pattern among HIV (Human Immunodeficiency Virus) outpatients in antiretroviral therapy (ART) centre of a tertiary care hospital. **Method:** We conducted a prospective, longitudinal follow up study of one year duration. Collected data was analyzed using descriptive statistics. **Results:** A total of 1491 prescriptions were collected from 250 HIV positive patients. Majority of the drugs were prescribed in oral dosage form. The average number of drugs per encounter was 4.26 and the average drug cost per encounter was INR 850.52. In majority of encounters (52.9%) first line HAART regimen was prescribed. The most common regimen prescribed among the first line HAART was the combination of Zidovudine, Lamivudine and Nevirapine (26.76%). The medication class most commonly prescribed were antiretroviral agents (39%). Antimicrobial agents were the second most common class of drugs prescribed (29.6%) with cotrimoxazole being the most common. The third most commonly prescribed drug class was vitamins (18.72%). There were total of 36 substitutions within the first line regimens with substitution of zidovudine by stavudine being the most common. In our study the optimal level of adherence as suggested by the national guidelines was achieved in 87.77% of encounters. **Conclusion:** Overall our results suggest that the prescribing pattern to be in accordance with national guidelines but there still remains a scope for improvement by using viral load as a biomarker instead of CD4 count. Also we would suggest a periodical external quality assessment of counsellors of all ART centres for further enhancement of adherence level.

**Key words:** Antiretroviral therapy centre, defined daily dose, drug use indicators, drug utilization study, human immunodeficiency virus

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## INTRODUCTION

Globally there were an estimated 34.0 million [31.4 million–35.9 million] people were living with HIV (Human Immunodeficiency viruses) at the end of 2011.<sup>[1]</sup> India has the third largest number of people living with HIV/AIDS. As per the 2008-09 HIV estimates, there are an estimated 23.9 lakh people currently living with HIV/AIDS (Acquired Immunodeficiency Syndrome) in India with an adult

prevalence of 0.31 percent in 2009.<sup>[2]</sup> 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 Programme (NACP) which provides a comprehensive prevention, care and treatment programme with standardized ART regimens at free of cost with a robust monitoring and evaluation system through various ART centres.

HIV is the initial causative agents in AIDS but most of the morbidity and mortality in AIDS cases result from opportunistic infections which necessitates polypharmacy. In addition to this high burden of the disease and lack of funds especially in developing countries, we conducted this study to determine the drug use indicators, adherence and opportunistic infections among HIV positive patients attending ART (Anti Retroviral Therapy) centre of a Government tertiary care hospital. 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 national guidelines and thus promoting rational drug use.

## MATERIALS AND METHODS

This was an observational, prospective, longitudinal follow up study conducted over a period of one year (January 2010 to December 2010) after approval from Institutional Ethics Committee, Shree M. P. Shah Medical College and Govt. G. G. Hospital, Jamnagar. Based on WHO (World Health Organisation) recommendations for sample size in drug utilization studies, we used a sample consisting of 250 patients having 1491 encounters.

All newly registered HIV positive patients registered with ART centre of our institute including all age groups of both sex including pregnant females and lactating mothers were included. At each encounter, after consultation by the treating physician, written informed consent was obtained and the patients were interviewed to get detailed information about their clinical status including opportunistic infections, drugs prescribed, adherence to therapy and possible adverse effects in the previous encounter. Adherence was checked by asking the patient if he/she had missed any doses and by counter checking the bottle containing anti retroviral drugs as per national guidelines. The level of adherence was estimated at the end of 30 days of treatment and was reported as >95% (less than 3 doses missed), 80-95% (3-12 doses missed), <80% (>12 doses missed).

The data so collected was analysed using descriptive statistics to determine drug use indicators and utilization pattern of drugs in HIV positive patients.

## RESULTS

A total of 1491 prescriptions were collected from 250 HIV positive patients out which majority (75.6%) belonged to the age group of 20-40 years. Prevalence was higher in males (62.8%) compared to females (37.2%). Majority (80%) of the patients had being diagnosed HIV positive for last 2 years. 130 (52%) were receiving HAART (High Active Anti Retroviral Therapy) and the rest 120 (48%) remained naive. Among the patients on HAART, 57.6% were receiving HAART regimens for last one year. Demographic characteristics of patients are summarized in Table 1.

**Table 1: Demographic characteristic of patients**

Characteristics	No. of patients (n=250)
Age (years)	
Range	2-72
Mean age $\pm$ SD	31.49 $\pm$ 15
Sex	
Male	157 (62.8%)
Female	93(37.2%)
Duration since diagnosed HIV positive (years)	
$\leq 2$	200 (80%)
2-4	34 (13.6%)
> 4	16 (6.4%)
Patients receiving HAART	130 (52%)
Patients not receiving HAART	120 (48%)
Treatment duration with HAART (years)	
$\leq 1$	75 (57.6%)
>1	55 (42.4%)

The average number of drugs per encounter was 4.26 with range of 0 to 12. In majority of encounters (60.54%) four or more drugs were prescribed. The average number of drugs prescribed to patients with duration of illness less than or equal to 1 year was 3.69, in comparison to 4.81 and 4.41 among patients having duration of 1 to 2 years and greater than 2 years respectively. WHO specified drug use indicators are given in Table 2.

In majority of encounters (52.9%) first line HAART regimen was prescribed. The most common regimen prescribed among the first line HAART was the combination of Zidovudine, Lamivudine and Nevirapine (26.76%) followed by Stavudine, Lamivudine and Nevirapine (10.53%) [Table 3]. The medications class most commonly prescribed were antiretroviral agents (39%), with nucleoside reverse transcriptase inhibitors (NRTIs) (25.96%), non-nucleoside reverse transcriptase inhibitors (NNRTIs)

(12.14%), protease inhibitors (PIs) (0.90%). Among antiretroviral agents, the most commonly prescribed NRTIs, NNRTIs, PIs were lamivudine (12.87%), nevirapine (8.62%), lopinavir/ritonavir (0.91%) respectively. Antimicrobial agents were the second most common class of drugs prescribed (29.6%). The most common antibacterial agent used was cotrimoxazole (18.58%), followed by antimycobacterial agents (9.3%). The third most commonly prescribed drug class in our study was vitamins namely folic acid and vitamin B complex tablets (18.72%) followed by ferrous sulphate (9.36%). The other less commonly used drugs included as miscellaneous were paracetamol (0.8%), chlorpheniramine (0.62%), ibuprofen (0.58%), ranitide (0.36%), calamine lotion (0.12%), antihypertensives (0.09%), antidiabetic agents (0.06%), bronchodilators (0.04%), albendazole (0.01%), gamma benzene hexachoride (0.01%) and valproate (0.01%) [Table 4].

**Table 2: Details on drug use indicators**

<b>Core indicators</b>	
<b>Prescribing Indicators</b>	
Average drugs prescribed	4.26
% of drug prescribed by generic names	81.42%
% of encounters with an antibiotic prescribed	79.54%
% of encounters with an injection prescribed	0.47%
% of drug from essential drug list	86.04%
<b>Patient care indicators</b>	
Average consulting time (min)	10.35
Average dispensing time (sec)	19.14
% of drugs dispensed	93.18%
Patient knowledge of correct dosage	87.46%
<b>Facility indicators</b>	
Availability of essential medicine list or formulary	Yes
Key drugs available	88.63%
<b>Complementary indicators</b>	
% of encounters treated without drugs	13.74%
Average drug cost per prescription (INR)	850.52
Drug cost on injections	6.38%

The first line regimens prescribed at the time of initiation of antiretroviral treatment were Zidovudine + Lamivudine + Nevirapine (56.16%), Zidovudine + Lamivudine+ Efavirenz (23%), Stavudine + Lamivudine + Nevirapine (12.3%) and Stavudine + Lamivudine + Efavirenz (7.69%). Since start of HAART, 98% patients had their CD4 count greater than 50% of the peak. There were total of 36 substitutions within the first line regimens with substitution of zidovudine by stavudine being the most common. Anemia was the most common reason for substitution [Table 5].

**Table 3: Utilization pattern of different HAART regimens**

HAART regimen	No. (percentage of encounters; n=1491)
<b>First line</b>	
Zidovudine + Lamivudine + Nevirapine	399 (26.76)
Zidovudine + Lamivudine + Efavirenz	158 (10.6)
Stavudine + Lamivudine + Nevirapine	157 (10.53)
Stavudine + Lamivudine + Efavirenz	75 (5.03)
<b>Second line</b>	
Zidovudine + Lamivudine + Tenofovir + Lopinavir/ritonavir boosted	14 (0.94)
Lamivudine + Tenofovir + Lopinavir/ritonavir boosted	15 (1)

**Table 4: Drug groups used in HIV positive patients at our ART centre on outpatient basis**

Drugs	No. (percentage of drugs prescribed; n=6354)
<b>Antiretroviral agents</b>	
NRTIs	1650 (25.96)
Zidovudine	575 (9.04)
Stavudine	228 (3.58)
Lamivudine	818 (12.87)
Tenofovir	29 (0.45)
NNRTIs	772 (12.14)
Nevirapine	548 (8.62)
Efavirenz	224 (3.52)
PIs	
Lopinavir/ ritonavir	58 (0.91)
<b>Antimicrobial agents</b>	
Antibiotic agents	1266 (19.92)
Cotrimoxazole	1181(18.58)
Amoxicillin+Clavulanic acid	19 (0.3)
Azithromycin	10 (0.15)
Levofloxacin	24 (0.3)
Ciprofloxacin	22 (0.3)
Silver sulfadiazine cream	10 (0.15)
Antimycobacterial agents	592 (9.3)
Isoniazid	198 (3.11)
Rifampin	198 (3.11)
Pyrazinamide	77 (1.21)
Ethambutol	113 (1.77)
Streptomycin	6 (0.09)
Antiprotozoal agents	29 (0.45)
Metronidazole	23 (0.36)
Nitazoxamide	6 (0.09)
Acyclovir	16 (0.25)
Antifungal agents	11 (0.17)
Fluconazole	9 (0.14)
Clotrimazole cream	2 (0.03)
Folic acid and Vitamin B complex	1190 (18.7)
Ferrous sulphate	595 (9.3)
Miscellaneous	175 (2.7)

**Table 5: Substitution within first line HAART regimen**

HAART Regimen Substitution	No. (percentage of encounters with substitutions; n=36)	Reason for substitution
Zidovudine to Stavudine		Anemia
ZLN to SLN	14 (38.89)	
ZLE to SLE	4 (11.11)	
Nevirapine to Efavirenz		Starting antituberculosis drugs/ nevirapine induced hepatotoxicity
SLN to SLE	8 (22.22)	
ZLN to ZLE	4 (11.11)	
Efavirenz to Nevirapine		Completion of tuberculosis treatment
ZLE to ZLN	4 (11.11)	
SLE to SLN	2 (5.56)	

In our study the level of adherence >95% which is considered optimal according to national guidelines was achieved in 87.77% of encounters. In 6.35% and 5.13% of encounters the level of adherence was 80-95% and < 80% respectively. In 0.75% encounters the bottle was not brought by patient hence adherence could not be estimated. Tuberculosis was the most common opportunistic infection [Table 6].

**Table 6: Occurrences of opportunistic infections among HIV positive patients**

Opportunistic infections	Incidence (%)
Tuberculosis	36 (26.86)
Upper Respiratory infections	27 (20.15)
Diarrhoea	21 (15.67)
Skin infections (boils)	10 (7.46)
Genital herpes	9 (6.72)
Candidiasis	8 (5.97)
Herpes zoster	7 (5.22)
Lymphadenopathy	5 (3.73)
Lower respiratory tract infections	3 (2.24)
Parotitis	2 (1.49)
Molluscum contagiosum	2 (1.49)
Kaposi carcinoma	1 (0.75)
Fungal skin infections	1 (0.75)
Pneumocystis carinii pneumonia	1 (0.75)
Scabies	1 (0.75)

## DISCUSSION

HIV has been a growing challenge worldwide. Increase in our understanding of molecular biology and pathogenesis of the disease has led to the development of a number of new antiretroviral drugs and treatment protocols which has changed the world's outlook on HIV/AIDS from a "virtual death sentence" to a "chronic manageable disease". This study is a pharmacoepidemiological research on the utilization of antiretroviral agents in real life conditions for identifying discrepancies between their actual use and our national guidelines which

are based on clinical trials. This will promote rational use of drugs.

The (mean ± SD) age of the patients was 31.49 ± 15 years with a range between 2 and 72 years. This higher prevalence of HIV among the sexually active and economically productive age group of 20-40 years is in accordance with other studies from India<sup>[3]</sup> and abroad.<sup>[4]</sup>

Prevalence was higher in males (62.8%) compared to females (37.2%) which is in consonance with other Indian studies.<sup>[3]</sup>

Majority of the patients had being suffering from HIV since at last 2 years [Table 1]. The mean duration was 20.1 ± 19 months with a range of 8 months to 97 months. 52% were eligible for initiation of HAART which is in consonance with another pharmacoepidemiological study.<sup>[5]</sup>

The average number of drugs per encounter was 4.26 in our study with range of 0 to 12 [Table 2]. Our results are in accordance with a similar study which analysed 967 encounters of HIV infected outpatients patients and found average number of drugs per encounter to be 4.5.<sup>[5]</sup> Moreover as HIV is associated with various opportunistic infections, poly-pharmacy is quite relevant leading to high average number of drugs prescribed. In 79.54% encounters an antibiotic was prescribed. Our results are in conformity with other studies.<sup>[5, 6, 7]</sup> It is clearly evident that the higher percentage of drugs prescribed by generic name and from essential drug list of WHO Model List of Essential Medicines for Adults, March 2011 point towards rational therapeutics. 0.47% of encounters with an injection prescribed were due to prescribing of the aminoglycoside streptomycin as part of tuberculosis treatment. In our study the higher percentage of patients having adequate

knowledge of correct dosage schedule is suggestive of increasing awareness and better compliance among HIV patients during past years. The availability of essential drug list is a better facility indicator of drug usage. Cost of prescription is important in chronic disease like HIV where drug has to be continued for life time. Average drug cost per encounter was 850.52 Indian National Rupees (INR) [Table 2]. The average annual cost of antiretroviral drugs in our study comes to 16,524.96 INR which is comparable to a study from South India in which the median annual costs of treatment for AIDS patients to be INR 17,606 with ARV.<sup>[9]</sup> The limitation of our study in calculating cost is that expenses incurred due to other than drugs were not considered.

The defined daily dose (DDD) is the assumed average maintenance dose per day for a drug used for its main indication in adults. Using DDDs enables comparison to be made between drug groups as the influences of prescribing culture and available dosage strengths are eliminated. This estimate is most useful for chronically used drugs.<sup>[10]</sup> DDD/1000 inhabitant/day of antiretroviral drugs prescribed could not be calculated as WHO has not assigned DDD for fixed dose combinations of antiretroviral drugs.

In majority of encounters (52.9%) first line HAART regimen was prescribed. The most common regimen prescribed among the first line HAART was the combination of Zidovudine, Lamivudine and Nevirapine (ZLN) (26.76%) followed by Stavudine, Lamivudine and Nevirapine (10.53%) (SLN) [Table 3]. The above finding is in accordance with our national guidelines for antiretroviral therapy which recommends ZLN as the first choice and SLN as second choice among all first line HAART regimens. Our results differ from a study done at Columbia in which the most common combinations prescribed were ZLE (35%), ZL+L/r (8.4%), ZLA (5.5%), ZLN (5.2%).<sup>[11]</sup> Another similar observational study from Asia found the combinations like SLN (37%), ZLE (13%), ZLN (9%), SLE (9%) were commonly prescribed.<sup>[12]</sup> This difference in prescribing rates of various regimens may be due to difference between the guidelines for antiretroviral therapy in various countries. The medications class most commonly prescribed were antiretroviral agents (39%), with nucleoside

reverse transcriptase inhibitors (25.96%), non-nucleoside reverse transcriptase inhibitors (12.14%), protease inhibitors (0.90%). All the doses were at recommended levels and majority of drugs were prescribed in oral dosage forms. Our results are in consonance with other studies in which majority of patients were prescribed nucleoside reverse transcriptase inhibitors followed by non nucleoside reverse transcriptase inhibitors and protease inhibitor.<sup>[4, 11]</sup> In consonance with another study among antiretroviral agents, the most commonly prescribed NRTIs, NNRTIs, PIs were lamivudine (32.98%), nevirapine (22.09%), lopinavir/ritonavir (2.33%) respectively [Table 4].<sup>[13]</sup> Antibacterial agents were the second most common class of drugs prescribed (29.6%) which is in consonance with other studies.<sup>[14]</sup> The most common antibacterial agent used was cotrimoxazole (18.58%), followed by antimycobacterial agents (9.3%). A similar type of study from Switzerland found cotrimoxazole to be the most common antibiotic being used.<sup>[5, 7]</sup> The increased use of cotrimoxazole is justifiable as it is recommended for chemoprophylaxis against pneumocystitis carinii pneumonia. Given the high rates of TB-HIV co-infection in our study, increased use of antimycobacterial agents is also justifiable. Like prior studies, the third most commonly prescribed drug class in our study was vitamins namely folic acid and vitamin B complex tablets (18.72%) followed by ferrous sulphate (9.36%) [Table 4].<sup>[14]</sup>

In our study the most commonly prescribed HAART regimen at initiation of antiretroviral treatment was Zidovudine + Lamivudine + Nevirapine (56.16%). This is in accordance to our national guidelines for starting HAART in HIV positive patients. The Stavudine based regimens were less preferred at initiation due to its toxicity profile. The second most common regimen prescribed at start was Zidovudine + Lamivudine+ Efavirenz (23%) which might be due to concurrent occurrence of tuberculosis. There were total of 36 substitutions within the first line regimens with substitution of zidovudine by stavudine being the most common [Table 5]. Our results differ from a study in South Africa where substitution of Stavudine with Zidovudine (38%) was the most common.<sup>[15]</sup> This variation might be due to difference in the pattern of drug usage. National guidelines recommend the usage of Zidovudine

based regimens over Stavudine as first choice unlike the South African guidelines.

Adverse events were leading cause for substitution in HAART regimens (58.3%). Anemia was most common adverse event responsible for substitution (50%) which is in conformity with another study.<sup>[16]</sup> However the results differ from a study carried in south India where rash was the most common cause.<sup>[17]</sup> This variation might be due to the preferential use of zidovudine based regimens in our study.

The efficacy of antiretroviral therapy (ARV) in suppressing viral replication and delaying the progress of the acquired immunodeficiency syndrome (AIDS) is related to strict adherence to treatment. Optimal adherence to the recommended regimens should be >95% to avoid development of ARV drug resistance.<sup>[18]</sup> In our study optimal level of adherence was achieved in majority of encounters (87.88%). Similarly studies from India and abroad also have observed a high level of adherence.<sup>[19, 20, 21]</sup> Several factors could explain the good adherence in our study. First, treatment was free of charge for all the patients under national AIDS control program phase III. Second, good drug procurement and distribution practices in our ART centre avoided disruption of drug supply. Third, our patients were adequately supported for improving adherence by counsellors in our ART centre. Very few studies have analysed outcome of ART in India's national ART programme.<sup>[22]</sup> In our study 98% of patients on HAART had their recent CD4 count greater than 50% of the peak CD 4 count value observed since start of HAART, which is comparable to a study from India.<sup>[22]</sup>

Even though human immunodeficiency viruses are the initial causative agents in AIDS, but most of the morbidity and mortality in AIDS cases result from opportunistic infections. Hence recognition of such pathogen is very important for clinicians and health planners to deal with the AIDS epidemic in more effective manner. In present study pulmonary tuberculosis (26.86%) was found to be the most common opportunistic infection. Majority of studies from India found pulmonary tuberculosis to be the most common opportunistic infection among people with HIV infection.<sup>[23, 24, 25, 26, 27]</sup> Understanding HIV-TB co-infection is of great significance because of increasing prevalence, rapid progression of HIV

disease in TB patients and challenges in treatment due to drug interactions and immune reconstitution syndrome.

## CONCLUSION

Studies on utilization pattern of drugs at ART centres appear to be lacking in our country. Thus this study provides a baseline data regarding the prescribing pattern, adherence profile, opportunistic infections and average drug cost among HIV positive patients registered at our ART centre. The prescribing pattern of HAART regimens was in accordance with our national guidelines for antiretroviral therapy. The provision of free treatment, good drug procurement and distribution practice and finally adequate counselling by the staffs at ART centre has lead to achieve the goal of optimal adherence. But we would suggest a periodical external quality assessment of counsellors of all ART centres for further enhancement of adherence among patients. Incidence of poly-pharmacy is relatively high which is quite relevant in our patients because of the associated opportunistic diseases and its complications. Along with this, drugs prescribed by generic name were also high therefore drug use in this set up is quiet rational. As in majority of ART centres decision treatment failure and switching are not based on viral load, which is a better biomarker of disease status than CD4 count. Hence we suggest increasing the facilities for detection of viral load to more ART centres.

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