A cross-sectional study of socio-demographic and clinical profile of HIV patients at ART plus centre, Sawai Man Singh Hospital, Jaipur, India

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Abstract
Background: This study aimed to understand the regional variation in the socio-demographic and clinical profile of human immunodeficiency virus (HIV) infected patients at antiretroviral therapy plus centre of Sawai Man Singh (SMS) hospital, Jaipur, India.

Methods: A descriptive cross-sectional study was conducted on HIV patients from January to December 2019. The HIV-positive patients of all age groups and all categories were included in the study. The socio-economic status was assessed by BG Prasad classification-based consumer price index. However, the clinical staging was done according to the World Health Organization (WHO) classification of HIV/AIDS. Data were expressed as mean ± standard deviation.

Results: Among 525 HIV patients 59.16% were males, 40.26% females and 0.57% intersex. About half (51.0%) in the reproductive age group with mean age 36 ±13 years. The commonest mode of HIV transmission was heterosexual (89.77%). Maximum belonged to social class I (57.84%) and class II (26.05 %) of BG Prasad's socioeconomic status. Each of the non-agricultural laborers and semi-skilled workers constitutes 18.0%, and the housewives were 23.6%. At the time of presentation, baseline CD4+ T-cell count was <350/mm3 in 55.0% of HIV patients. Pulmonary tuberculosis and skin involvement were the most predominant secondary opportunistic infections accounting for 24.8% and 7.8%, respectively. More than half (52.09%) of patients were in WHO clinical stage I of HIV disease.

Conclusion: Socio-demographic and clinical profile of study participants reflect an impact of early case detection and timely institution of highly active antiretroviral therapy.

Keywords: Clinical Profile HIV, Socio-demographic Profile HIV, Opportunistic Infection, Antiretroviral Therapy, India

Background
Acquired immunodeficiency syndrome is a chronic, potentially life-threatening condition caused by the human immunodeficiency virus. It harms the immune system by destroying white blood cells such as CD4+ T cells (T-helper cells), dendritic cells, and macrophages. As the number of clusters of differentiation 4 (CD4+) cells in the body decreases, the immune system gets collapsed and leads to the risk of developing opportunistic infections and certain malignancies. According to the Joint United Nations Program on HIV/AIDS and World Health Organization Report 2020, around 38 million people are living with HIV/AIDS worldwide, some 1.7 million people were newly infected with the virus, and 690 thousand people died of HIV related illness in 2019 [1].

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India has the third-highest burden of HIV in the world. It is estimated by the annual report 2018-2019 published by the Department of Health and Family Welfare, Government of India, that the total number of People Living with HIV (PLHIV) in India is 21.40 lakhs (lakh is a unit in the Indian numbering system equal to one hundred thousand). An estimated 87 thousand new HIV infections and 69.11 thousand people died of AIDS-related causes nationally in 2017 [2]. National adult HIV prevalence in India is estimated at 0.22% (0.16%–0.30%) with range of 0.25% among males and 0.19% among females. Rajasthan is among the States /UTs, having less than 1 lakh people living with HIV with a prevalence lesser than the national average [3]. HIV/AIDS is one of the most severe socio-economic concerns because most of the affected population is from economically productive age group and occurring in sexually active persons with high-risk behavior. The World Bank has categorized India as a low-income country. Approximately 70.0% of its people live in rural areas.
The critical factors responsible for the disease's spread are ignorance about the disease, fear of discrimination, and consequent avoidance for testing and treatment. Females do not seek medical care in fear of eviction, making them more vulnerable to the disease. The most common occupation group infected with HIV is the labor group, including the skilled and semi-skilled workers and agricultural laborers, truck drivers, and local transport workers. The reason behind their infection is moving to the metropolitan cities, staying away from their spouse for more extended periods, having poor awareness, and lower literacy. India launched its free national antiretroviral therapy program in April 2004, which is the cornerstone of managing patients with HIV/AIDS infection. Opportunistic infections (OI) are becoming a predominant cause of morbidity even with ART's widespread use and prophylaxis to these infections. Tuberculosis (TB) is the most reported OI among HIV-infected patients in India. Oral candidiasis, diarrhea, pneumocystis jiroveci Pneumonia, herpes simplex, herpes zoster, respiratory and skin bacterial infections, cryptococcal meningitis, cytomegalovirus retinitis are other commonly reported OIs [4,5]. There is regional variation in the demographic and clinical presentation of HIV disease and the spectrum of opportunistic infections of HIV patients. Under this background, we studied the socio-demographic and clinical profile of HIV patients.

Methods
A descriptive cross-sectional study was conducted at antiretroviral therapy (ART) plus the centre of Sawai Man Singh (SMS) Hospital Jaipur, Rajasthan, India, from January to December 2019. The ART plus center was established on 05 October 2005, occupying 2750 yards with complete diagnostic (hematological and radiological) workup facilities for all PLHIV free of cost. ART plus the centre of SMS Hospital is affiliated with The National Aids Control Organization (NACO) and has facilities for first-line ART, alternate first line, second line, third line ART, and drugs for managing all opportunistic infections along with trained staff for counseling and management of HIV patients.

Inclusion and exclusion criteria
The HIV-positive patients on highly active antiretroviral therapy (HAART) were randomly selected based on inclusion and exclusion criteria. HAART is a “treatment regimen typically comprised of a combination of three or more antiretroviral drugs therapy”. The HIV-positive patients of all age groups and all categories were included in the study. Those with missing data and not willing to give consent were excluded from the study. Enrolled HIV patients were studied for demographic details including age, sex, residence, education level, occupation, socio-economic status, marital status, HIV status of spouse, mode of transmission, and for clinical profile including presenting symptoms, WHO clinical stage, CD4 count, opportunistic infections at the time of presentation and ART regimen.

Socio-economic status and clinical staging of the patients
The Socio-economic status was assessed by the BG prasad classification-based consumer price index [6]. It applies to both urban and rural populations. It is based on per capita monthly income and is widely used in India. According to the World Health Organization (WHO), clinical staging of the patients was done according to the World Health Organization (WHO) classification of HIV/AIDS [7]. HAART therapy was given to the patients by the Doctor of ART centre, depending on eligibility as per NACO guidelines. The patients were given ART regardless of their CD4 count under the new ART guidelines [7].

Sample size calculation
The sample size was calculated for 95% confidence limit, 80.0% power and 8.5% relative error as per previous studies [8], giving the final sample of 525 HIV cases.

Statistical analysis
The descriptive statistics of quantitative data were expressed as mean and standard deviation. The association between qualitative attributes was estimated with a coefficient of contingency (C). The value of 'C' varies from 0 to 1(for an infinite number of classes). There is no strength of association when the coefficient of contingency is zero (C=0). The baseline CD4 count was divided into three categories: baseline level less than 350 /µl, baseline level between 350 – 500 /µl, and baseline level greater than 500 /µl. The associations of baseline CD4 categories with opportunistic infections were analyzed. Statistical significance was tested with Chi-square tests at a 5% level of significance (α=0.05). The JASP 0.11.1.0 statistical package was used for statistical analysis.

Results
A total of 525 patients were enrolled in this study with a mean age of 36 ±13 years. More than half (59.16%) of participants were males, married (81.13%), primary school education (60.66%). According to BG Prasad Score, more than half (57.84%) of participants from the socio-economic Status I. Heterosexual mode of HIV/AIDS transmission prominent among 89.77 of the studied sample (Table 1). The leading age group affected with HIV/AIDS was from the reproductive age group that is 21 - 40 years (51.0%), and 11.26 % of patients belonged to the pediatric age group, as shown in figure 1(a). ART centre of SMS Hospital, Jaipur, caters to HIV patients not only from the native state of Rajasthan (92.0%) but also from border states of Haryana (2.4%) and Uttar Pradesh (UP) (2.6%) and other states like Delhi, Bihar, and MP. Among the districts of Rajasthan apart from Jaipur district (45.0%), HIV patients attended ART centre were residential from Tonk (12.0%), Dholpur (9.0%), Karauli (7.6%), Sikar (7.4 %), Sawai Madhopur (7.2%), Dausa (4.0 %) and Alwar (2.0 %) as shown in figure 1(b). The commonest mode of transmission was the heterosexual route (89.7 %). Among 81.0% married HIV patients, spouses of 53.4% were found HIV positive. In contrast, vertical transmission (mother to child) accounted for (6.74 %) cases of HIV transmission. Considering the occupation of HIV patients, the highest percent was among the housewives (24.0%), non-agricultural laborers (19.0%), and skilled workers (19.0%) respectively. However, lowest percent found among the students (8.0%), local transport workers (7.0%), and truck drivers (6.0%) respectively.
Clinical profile of HIV/AIDS patients shows that 56.0% were having baseline CD4 count < 350 cells/µl while 44.0% were having CD4 count between >350 and <500 cells/µl. Most of the patients belonged to WHO clinical stage I (52.0%) and stage II (28.0%). More than half (55.3%) were asymptomatic at presentation. The most frequent presenting symptoms were fever, weight loss and cough (22.1%), persistent diarrhea, oral candidiasis, and encephalitis found a significant inverse correlation ($P < 0.05$) with baseline CD4 count. Pneumocystis pneumonia, Toxoplasmosis, and malignancies develop late in the illness, so not having a positive correlation ($P < 0.05$) with baseline CD4 count (Table 2).

**Discussion**

The database search retrieved six citations. There were no duplicates. Four articles not matching the eligibility criteria were excluded. The adjunct search in the bibliography of the reviewed trials did not reveal any additional articles. Figure 1 demonstrates the study selection process. In this systematic review, we included two RCTs matching the above inclusion criteria. These trials sourced data from about 833 COVID-19 patients from 115 hospitals in Asia, Europe, and the US [15,16]. In both the trials, the patients received the intravenous remdesivir of 200 mg on the first day and 100 mg on the successive nine days [15,16]. In one trial, some participants received the regimen for five days (instead of 10 days) [16].  

(i) Trimethoprim-Sulfamethoxazole prophylaxis was given to prevent Pneumocystis Carinii pneumonia in all patients with a CD4 lymphocyte count of <350 cells/µl. Isoniazid prophylaxis was given to all new patients till 2-3 weeks of ART. In the case of patients who developed resistance to these first-line regimens (clinical failure, immunological failure, or virological failure) were switched to second-line antiretroviral therapy, containing boosted protease inhibitors (PI), e.g., Atazanavir / Ritonavir or Lopinavir/ Ritonavir combination. 

Tuberculosis, oral candidiasis, and encephalitis found a significant inverse correlation ($P < 0.05$) with baseline CD4 count. Pneumocystis pneumonia, Toxoplasmosis, and malignancies develop late in the illness, so not having a positive correlation ($P < 0.05$) with baseline CD4 count (Table 2).

**Table 2** Association between baseline CD4 and other attributes are calculated with a coefficient of contingency.

| Opportunistic Infection | Chi-square | Coefficient of Contingency | P-value |
|-------------------------|------------|----------------------------|---------|
| Tuberculosis            | 10.82      | 0.142                      | 0.004   |
| Skin Infections         | 2.76       | 0.072                      | 0.251   |
| Oral                    | 6.91       | 0.114                      | 0.032   |
| Candidiasis             | 2.38       | 0.067                      | 0.304   |
| Bacterial               |            |                            |         |
| Pneumonia               |            |                            |         |
| Encephalitis            | 7.22       | 0.117                      | 0.027   |
| Baseline CD4 Count      |            |                            |         |
| Diarrhea                | 3.28       | 0.079                      | 0.194   |
| Toxoplasmosis           | 2.44       | 0.068                      | 0.295   |
| Malignancies            | 2.25       | 0.065                      | 0.325   |
| Tuberculosis            | 10.82      | 0.142                      | 0.004   |

**Table 1** Demographic characteristics of patients with HIV/AIDS (n=525)

| Variables                  | Categories       | N   | %    |
|----------------------------|------------------|-----|------|
| Age group                  | 0-20             | 59  | 11.26|
|                            | 21-40            | 268 | 51.14|
|                            | 41-60            | 175 | 33.40|
|                            | ≥60              | 22  | 4.20 |
| Gender                     | Female           | 211 | 40.27|
|                            | Intersex         | 3   | 0.573|
|                            | Male             | 310 | 59.16|
| Marital status             | Divorced         | 15  | 0.465|
|                            | Married          | 301 | 81.13|
|                            | Single           | 37  | 9.97 |
|                            | Widow            | 18  | 4.85 |
| Educational status         | College          | 83  | 17.01|
|                            | Illiterate       | 45  | 9.22 |
|                            | Primary          | 296 | 60.66|
|                            | Secondary        | 58  | 11.89|
|                            | Senior Secondary | 6   | 1.23 |
| Socio-economic Status      | Senior Secondary | 6   | 1.23 |
| Status (BG Prasad Score)   | I                | 273 | 57.84|
|                            | II               | 123 | 26.06|
|                            | III              | 66  | 13.98|
|                            | IV               | 4   | 0.85 |
|                            | V                | 6   | 1.27 |
| Mode of transmission       | Heterosexual     | 386 | 89.77|
|                            | Homosexual       | 11  | 2.56 |
| Intravenous Drug Use       | Nil              | 4   | 0.93 |
| Mother to Child            | Nil              | 29  | 6.74 |
| Blood transfusion          | Nil              | 29  | 6.74 |

The most predominant opportunistic infection among which pulmonary tuberculosis and skin involvement were more predominant, accounting for 24.8% and 7.8%, respectively shown in figure 2(b). As per NACO guidelines, all eligible patients were given antiretroviral therapy, which included a standard first-line regimen: (i) Tenofovir (TDF 300 mg) + Lamivudine (3TC 300 mg) + Efavirenz (EFV 600 mg) (TLE) as Fixed Dose Combination (FDC) in a single pill once a day.

**OR**

Zidovudine (ZDV 300 mg) + Lamivudine (3TC 150 mg) + Nevirapine (NVP 200 mg) / Efavirenz (EFV 600 mg). The zidovudine-based regimen was given to those patients who were initiated earlier in the program.

(ii) Trimethoprim-Sulfamethoxazole prophylaxis was given to prevent Pneumocystis Carinii pneumonia in all patients with a CD4 lymphocyte count of <350 cells/µl. Isoniazid prophylaxis was given to all new patients till 2-3 weeks of ART. In the case of patients who developed resistance to these first-line regimens (clinical failure, immunological failure, or virological failure) were switched to second-line antiretroviral therapy, containing boosted protease inhibitors (PI), e.g., Atazanavir / Ritonavir or Lopinavir/ Ritonavir combination.
Discussion

In our study, the mean age of HIV patients was 36 ±13 years, with male predominance (59%). These findings are like the study conducted at SP Medical College Bikaner Rajasthan [8], in which the mean age of HIV patients was 36.64 ±12.25 years, with a male population (57.66%) outnumbered in the study. Another study was done at Sardar Valabhbai Patel Hospital, Meerut in western UP [9] found the results at par with our study. In our study, 51.0% of patients were in the reproductive age group (21–40), while the study conducted at the Institute of Medical Sciences, Banaras Hindu University, Varanasi [10] found that 78.0 % of patients were in this age group. The heterosexual route was the commonest mode of transmission of HIV infection. These findings were remarkably similar to most previous studies conducted on the socio-demographic profile of HIV patients [8-12]. Emphasizing that if specific measures are applied like encouraging people to adopt and maintain risk reduction strategies, including condom use, adherence to HIV treatment, and sterile injection practices, it can decrease HIV transmission as per cited on HIV gov [11]. A female spouse was found more vulnerable to HIV infection than a male spouse from their partner. Similar findings seen in the study conducted in a rural tertiary care hospital in Maharashtra [12], wherein the spouse positivity was higher among females. These observations could be because in females, a larger surface is exposed, and semen contains a higher concentration of HIV than vaginal or cervical fluids. In our study majority of patients belonged to social class I. However, they were in social class I, and the draw per capita monthly income around 7000– 8000.
contradictory to the study conducted at rural tertiary care hospital Maharashtra [12], in which most patients belonged to social class III & IV (modified B.G Prasad's social classification). The education of HIV patients in our study found that 90% of patients were literate, and only 9.8% were illiterate. Among literates, the maximum number of patients (60.65%) were educated only up to the primary level, while a study was done at Lok Nayak hospital, New Delhi [13] found that a total of 82.0% of HIV patients were literate and only 16.0% had primary level of education. Therefore, it is inferred that the education level should be raised adequately to obtain knowledge for HIV protection.

The overall spectrum of opportunistic infection in our study is similar to previous studies done at the Institute of Medical Sciences, Banaras Hindu University, Varanasi [10], and at Gauhati Medical College [14]. However, the percentage of the patients with tuberculosis, candidiasis, and diarrhea were lesser when compared to above mentioned studies. Nevertheless, tuberculosis was the most common opportunistic infection in the present study, which matches with studies done in other parts of India [8-15]. In our country, where tuberculosis is endemic, many people are infected with TB in childhood. The immune system breaks down, as in HIV, tuberculosis becomes active. Severe or recurrent skin infections like warts, dermatophytosis, pruritic dermatitis, and herpes zoster or shingles presenting with localized pain and burning sensation followed by vesicle eruption, orpharyngeal candidiasis, or oral thrush (caused by a common yeast fungus, presents with soreness and redness with a white plaque on the tongue, back of the mouth or on throat), chronic diarrhea and severe weight loss were another OI in our study.

It was found that candida esophagitis, cryptococcus meningitis, and parasitic infections such as pneumocystis carinii pneumonia or toxoplasma gondii encephalitis tend to occur when CD4 cell count has dropped to around 100. The present study shows that 45.0% of our patients were diagnosed through clinical symptoms, while 55.0% of patients were asymptomatic at the time of presentation and were diagnosed during routine scanning or came for testing due to high-risk behavior. Most of the patients were in WHO clinical stage I (52.0%) and II (28.6%), which means most patients in the study were at a relatively good immune status and in the early stage of the disease. This shows an impact of early case detection and timely institution of highly active antiretroviral therapy (HAART). These findings are similar to the study done in Lok Nayak hospital in New Delhi [13] but contradictory to the study done in the rural tertiary care hospital in Maharashtra state [12], where 42.5% of patients were in stage III.

A previous study at Clinical Hospital Doutor Serafim de Carvalho, Southwestern Goias, Brazil [16] found the mean age of presentation was 39.5±11 with male predominance, heterosexual route as a common mode of transmission in HIV patients, these findings were in concordance with our study. This study also [16] found pneumonia caused by Pneumocystis jirovecii was the most predominant OI, while in our study, tuberculosis was common OI among HIV patients. Our study’s limitation was that it was conducted at a single tertiary care center with limited sample size. A multi-centric study on a large population is warranted for validation of results.

Conclusion
Most of the patients were from the reproductive age group, semi-skilled workers, and truck drivers and had a primary education level. Our study also found that most of the patients were asymptomatic at the time of presentation, and the majority of the patients were in WHO clinical stage I and II at the time of presentation, with a lesser number of patients were affected with an opportunistic infection this reflects an impact of early case detection and timely institution of highly active antiretroviral therapy (HAART). The study recommends the importance of accurate information about disease prevention, especially among spouses of affected patients and people with high-risk behavior. The study’s data will help health care professionals for effective case management and policymaking for the institution.

Abbreviation
HIV: Human Immunodeficiency Virus; NACO: National AIDS control organization; WHO: World health organization; OI: Opportunistic infection; ART: Antiretroviral Therapy; TB: Tuberculosis; PLHIV: People Living with HIV; HAART: Highly Active Antiretroviral Drugs; CD4: Cluster of Differentiation 4; UP: Uttar Pradesh

Declaration

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Availability of data and materials
Data will be available by emailing jaincharujaincharu2007@gmail.com

Authors’ contributions
Authors have contributed equally to the study concept, design, writing of the original draft. Amit Tak participated in the statistical analysis of the data. Monika Jain reviewed and edited the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate
We researched the Declaration of Helsinki, and the protocol was approved by the institutional ethics committee (IEC 4122/MEC/EC/2018, dated 9/10/18) SMS. Medical College Jaipur, Rajasthan, India.

Consent for publication
Not applicable

Competing interest
The authors declare that they have no competing interests.

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