Epidemiological trends in patients living with human immunodeficiency virus: a 13-year experience from a tertiary care center in India

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SUMMARY

With significant advancement in the tools and strategies available for diagnosis and management, there is an expected change in the epidemiological profile of patients living with HIV/AIDS (Human immunodeficiency syndrome/Acquired immunodeficiency syndrome). We retrospectively analyzed the changing epidemiological pattern of HIV infection over a period of 13 years in the anti-retroviral (ART) center of a tertiary care hospital in India. The study included a total of 9419 patients (8811 adults and 608 children) who were registered at our ART center between 2005 and 2017. Among adult patients, 68.9% patients were males and the mean age of presentation was 35.6±9.9 years. Heterosexual route was the most common route of transmission (95.5%). A total of 97.4% of pediatric patients acquired HIV infection via vertical transmission from their mothers. Most of the adult patients (77.1%) were educated only to primary level. Despite the economic growth in the country over the years, the monthly income of these patients has not significantly changed. The median CD4 count at the time of eligibility for starting ART was 244/μl of blood. An increasing trend in the baseline CD4 count was noticed from 2005 to 2017. Also, improved outcomes with less loss to follow up were noticed in the latter years. However, an increasing trend was also noted in the time gap between registration at the ART center and initiation of ART. Improvement in the baseline CD4 count and better treatment outcomes are indicators of a well-functioning national program. However, continued programmatic interventions are needed to further tackle the menace of HIV/AIDS in India.

***Keywords*:** Parent to child transmission; CD4 count; anti-retroviral therapy.

INTRODUCTION

Over the last decade, significant changes have occurred in the epidemiology of people living with Human Immunodeficiency Virus (HIV). The first few human cases of HIV were reported in the early eighties [1]. Since then, it has evolved into a global epidemic. Huge strides have been taken in understanding the pathogenesis of this disease. Acquired immunodeficiency syndrome (AIDS) no longer remains unmanageable. The management of this disease has drastically changed from less effective single drug therapy to multiple pill therapy to highly active single pill therapy containing multiple drugs of different classes. With continuous advancement in the diagnostic and management strategies, there is an expected change in the epidemiology of the disease [1].

HIV is a leading public health problem in India [2]. The total number of patients living with HIV infection in India is one of the highest in the world (2.1 million in 2013) [3]. The National AIDS Control Program (NACP) in India is a government

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sponsored program for the prevention and control of HIV & Acquired immunodeficiency syndrome (AIDS) in the country. The number of new HIV infections in India in the year 2015 was around 86000 which is 32% less than what it was in the year, 2007. Since 2007, the number of AIDS related deaths have declined by 54% [4]. The antiretroviral therapy (ART) provided free of cost under the National AIDS Control Organization (NACO) has also undergone significant change over these years. The two basic regimens available in the earlier years consisted of lamivudine and nevirapine along with either stavudine or zidovudine. They were effective but often had serious adverse effects. In 2014, the policy was modified and patients diagnosed with HIV were started on tenofovir, lamivudine and efavirenz. The patients stable on either zidovudine or stavudine were continued on the original regimen. The timing of initiation of anti-retroviral therapy has also changed considerably over the last few years. In the early years, ART was initiated if the CD4 count was less than 200/μl, but the cut-off was slowly increased to 350/μl and then 500/μl. In the landmark START trial, it was documented that early initiation of ART leads to better outcome in PLHA [5]. Therefore, in the month of April 2017, the Ministry of Health and Family welfare, Government of India launched the "test and treat" policy in which all the HIV patients were to receive anti-retroviral therapy irrespective of their CD4 counts [6]. The program is moving continuously and progressively towards better strategy of diagnosis and management. This coupled with the improvement in the socio-economic profile of the Indian patients has put the national program on the right path. However, the program has some ground to cover in their endeavor to provide the best possible care to the PLHA population. The present study is aimed at comprehensively delineating the epidemiology of HIV and observing the trend over the years, in an anti-retroviral therapy clinic linked to a tertiary care center in North India.

PATIENTS AND METHODS

A retrospective review of records (2005 to 2017) was done, whereby, data from all patients registered at the anti-retroviral center (under the aegis of NACO) of All India Institute of Medical Sciences, New Delhi was analyzed.

Patients who were suspected with HIV were diagnosed based on third generation enzyme linked immunosorbent assay (three different assays with different target or principle). HIV exposed babies were tested by HIV DNA polymerase chain reaction assay (PCR) of dry Blood Spot (DBS) at 6 weeks of age. If the test was positive, a repeat HIV DNA PCR of DBS was done to confirm the infection. All those who were confirmed as retro-positive and registered at our center with a baseline CD4 count in the records were included in the study. Those patients with incomplete demographic details were excluded from the study. All cases of suspected HIV that were referred to the ART clinic were confirmed at the program approved Integrated Counselling and Testing Center (ICTC). The patients were registered after confirmation at ICTC. There were assigned two types of registration - "Pre-ART" or "ART". The demographic details (age, gender), possible route of transmission {Heterosexual/ Mother to Child/Others (including men who have sex with men, intravenous drug use etc.)}, education level (Illiterate/Primary/Secondary & Collegiate) and monthly income in Indian Rupees (INR) were recorded. A baseline clinical, epidemiological and laboratory evaluation was done in all registered patients. A CD4 count was also done at that time using flow cytometry. If the CD4 count was more than the cut-off decided by the program at the time the patient came to the clinic, they were "Pre- ART" registered and asked to follow up with repeat CD4 counts at regular intervals. They were shifted to "ART" registration and started on treatment, if and when the CD4 count fell below the said "cut-off". If the CD4 count was below the cut-off at the outset, the patients were "ART" registered and started on treatment right away. The ART was started after a mandatory set of clinical, laboratory and radiological evaluation was complete. The time period between the time of registration and the time of initiation of treatment was recorded. The regimen comprised of two nucleoside reverse transcriptase inhibitors and one nonnucleoside reverse transcriptase inhibitor (efavirenz or nevirapine). The current outcomes of the patient as of December of 2017 was also recorded - Alive on ART/Died/Transferred out/Loss to follow up. Of those, who were alive on ART, the regimen details were also collected.

Statistical analysis

Continuous data were presented as mean ± standard deviation (for normally distributed variables) or median and interquartile range when standard deviation was more than 50% of the mean (extremes of data). The frequency of categorical variables was expressed in numbers and percentage. The data analysis was also done separately for each year to see the epidemiological trend. All analyses were done using SPSS (version 21) (SPSS Inc., USA).

RESULTS

A total of 10,868 patients were registered at our ART center between 2005 and 2017. A total of 9419 of these patients were included in the study. This included 8811 adults and 608 children (age ≤18 years). The rest were excluded because of missing baseline CD4 or demographic data.

Among adult patients the mean age at the time of presentation was 35.6±9.9 years (Table 1). Males (n=6074, 68.9%) were the predominant population

Table 1 - Demographic profile of adult patients (age >18 years) with HIV infection.

Year	*Number*	*Mean age in years*	*Median monthly income (in Indian Rupee)*	*Gender (%) (Female/Male/ Transgender)*	*Transmission (%) (Heterosexual/ Mother to Child/ Others)*	*Education (%) (Illiterate/Primary/Secondary or collegiate)*
2005	577	36.0	6500	26/73.5/0.5	97.9/0.005/2.09	7.0/73.4/19.5
2006	750	34.6	8000	29.6/70.4/0	98.5/1.49/0.002	2.9/80.8/16.2
2007	1058	34.4	7900	31.5/68.4/0.1	97.5/2.49/0.006	14.6/73.6/11.8
2008	857	34.5	7000	29/70.8/0.2	97.5/2.49/0.002	3.6/77.5/18.9
2009	558	34.8	6000	31.7/67.2/1.1	93.0/0.02/6.97	11.7/66.1/22.2
2010	663	35.5	6500	33.9/65.9/0.2	97.2/2.79/0.01	5.7/80.0/14.3
2011	613	36.6	6500	32.6/67.2/0.2	97.8/2.19/0.004	5.5/90.7/3.8
2012	520	35.7	6500	35.0/65.0/0	97.8/2.2/0.0	4.9/89.8/5.3
2013	570	36.3	7000	29.4/69.8/0.8	92.9/0.01/7.09	11.5/81.0/7.5
2014	612	36.3	5000	31.8/68.2/0	96.4/3.59/0.01	2.6/89.0/8.4
2015	641	35.5	7500	30.1/69.7/0.2	95.1/0.02/4.8	4.9/80.9/14.2
2016	734	36.4	8000	29.0/70.5/0.5	91.0/0.02/8.96	3.7/67.7/28.6
2017	658	37.1	8500	31.3/68.2/0.5	86.1/0.01/13.8	14.7/57.5/27.8
Total	8811	35.6	7000	30.7/68.9/0.4	95.5/0.02/4.48	7.4/77.1/15.5

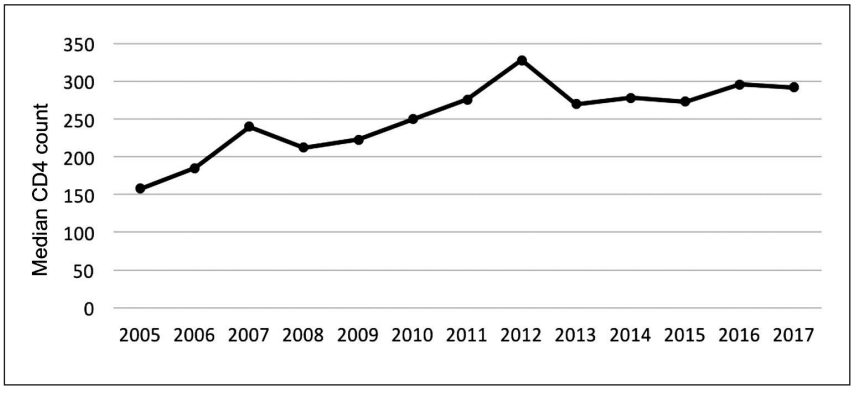

Figure 1 - Median CD4 count (per µl) at the time of presentation in patients with HIV.

through-out the thirteen years of the study (Table 1). Most common route of transmission was heterosexual transmission (n=8415, 95.5 %) (Table 1). The median monthly income of the patients presenting to our clinic was only INR 7000 (4500-10000). Most patients (n=6807, 77.1%) had education up to only primary school level (Table 1). There were 608 patients (6.4% of the total patients) in the pediatric age group (age ≤18 years). A total of 67% (n=409) of these patients were male. A total of 97.4 % of these children acquired infection via vertical transmission from their mothers.

The baseline median CD4 count (interquartile range in bracket) at the time of eligibility for anti-retroviral therapy was 244 (121-435)/µl of blood. An upward trend was noted in the baseline CD4 count from 2005 to 2017 (Figure 1). The median time duration between ART registration and initiation of ART was 10 (5-25) days. There was an upward trend noted in the time duration between registration and initiation of ART (Figure 2).

Out of a total of 9419 patients, 5896 patients were "ART" registered. The rest of the 3523 patients were only pre-ART registered. They either died, transferred out or were lost to follow up before they could become eligible for "ART" registration. Out of the 5896 patients registered on ART, 3616 (61%) were alive on ART by the end of 2017. An increasing trend was noted in the number of patients who were alive on ART. At the same time, a falling trend was noticed in the number of deaths and the number of patients, who were lost to follow up (Figure 3). Of those who were alive on ART, most of the patients were on efavirenz based regimen (n=2211, 61%) followed by nevirapine based regimen (n=1211, 33%).

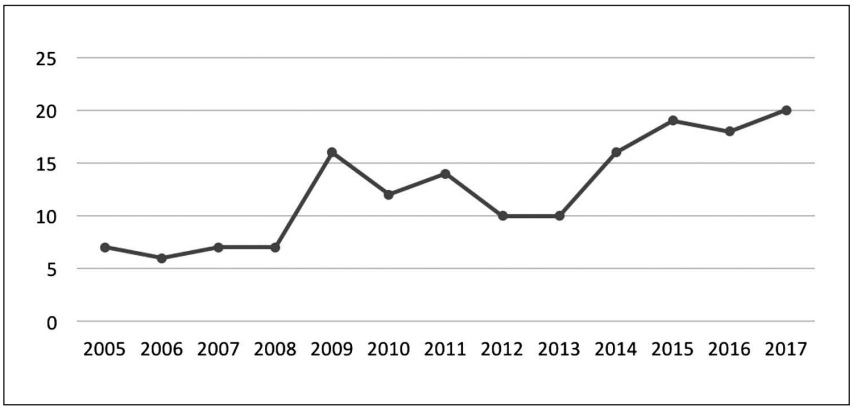

Figure 2 - Median delay (in days) between registration and initiation of treatment.

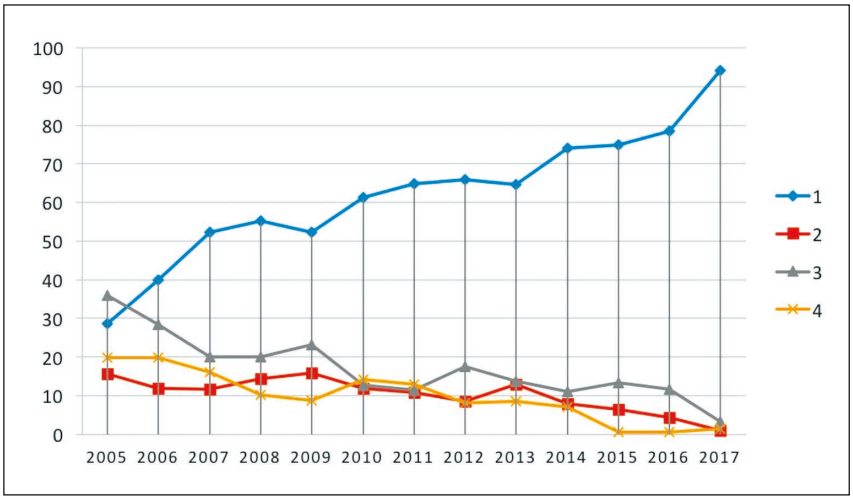

Figure 3 - Trend of outcomes (expressed in percentage) by the end of 2017 in "ART" registered patients.
*1-alive on ART 2-died 3-transferred out 4-lost to follow up.

DISCUSSION

Most of the studies on epidemiology of HIV from India are small, ranging over a small period of time [7-13]. We previously published large studies on the predictors of poor outcome in HIV-tuberculosis co-infected patients, immune reconstitution inflammatory syndrome and malignancies in HIV, but large scale studies on epidemiological profile of HIV in India are lacking [14-16]. Ours, although retrospective, was an analysis of data from more than 9000 patients. We have examined the epidemiological trend over ten years to evaluate the efforts of this ART center in controlling the HIV epidemic. We expect this study to serve as a stepping stone for more comprehensive prospective cohort studies from India.

The mean age of presentation in our study was 35.6 years which has remained largely unchanged over the last 13 years. Similar findings have been observed in other Indian studies with most of the newly diagnosed persons belonging to the age group of 25 to 49 years [13-17]. Like other previously published studies, our patients were predominantly represented by the male gender [13-17].

Even though, the gross domestic product of the country is rising, the mean monthly income of the HIV population has remained low over the past thirteen years. Similar results were observed in previous studies from other parts of India [17]. Most of our patients had only primary level education. This again underlines the fact that HIV predominantly affect the most vulnerable, socio-economically and educationally backward sections of the society. There is a need to devise better strategies to promote understanding and acceptance of safe behaviors in the low socio-economic population. This includes safe sexual and injection practices. Information, education and communication (IEC) activities should be devised keeping in mind the education level of the target population. Imparting sex education at an early age may be required to disperse the message of condom use and HIV prevention in these "at risk" population. Night schools and mass education program can be used as other channels through which awareness about HIV can be created.

Heterosexual transmission continues to be the main mode of HIV transmission. In the pediatric age group, majority of the infections were acquired through vertical transmission from their HIV infected mothers. The strategy for prevention of parent to child transmission (PPTCT) of HIV in India has undergone significant change over the years. During the initial years, single dose nevirapine was the prophylaxis given for both the pregnant woman (at the time of labor) and her new born infant. In the recent past, NACO changed its strategy according to the WHO guidelines and recommended that all pregnant women should be started on life-long triple drug ART [18]. With the improvement and better implementation of national guidelines, maternal to child transmission is decreasing. In a review of pediatric HIV in India, similar to our results, it was reported that pediatric patients constitute 7% of total HIV cases and more than 90% of these cases are due to maternal to child transmission [19].

The median baseline CD4 count at eligibility was 244/μl of blood with an increasing trend noticed from 2005 to 2017. Until 2017, India has been following the 2010 WHO recommendations, where all PLHIV with CD4 counts ≤350 cells/mm^3, or with TB co-infection or evidence of active hepatitis and all children aged under 5 years are initiated on ART [20]. The second edition of the WHO's consolidated guidelines on the use of anti-retroviral drugs for treating and preventing HIV Infection (2016) recommended initiation of ART in all adults living with HIV, regardless of WHO clinical stage and at any CD4 cell count [19]. This recommendation was based on the findings of various studies, predominantly the START and the TEMPRANO trial which showed that initiating ART at a CD4 cell count above 500 cells/mm^3, in the absence of other treatment indications, leads to less severe HIV morbidity (combined outcome of death, AIDS and severe non-AIDS diseases such as malignancies and bacterial diseases) compared with treatment initiation at a CD4 cell count at or below 500 cells/μl [21]. The policy of "Test and Treat" in the treatment of HIV was therefore, adopted by the NACO in April, 2017. This is probably, one of the contributing factors, as to why the median CD4 count at initiation of ART was higher in the latter years. However, for the increase to be furthermore significant, other strategies have to be employed, such as, efficient screening and surveillance in high risk as well as general population. The Centre for Disease Control (CDC) recommends HIV testing in all individuals at least once in life time while

HIV is tested in India, only, if there is a suspicion based on high risk behavior or clinical symptomatology. There is a possible need to review and revisit this strategy.

There has been a significant change in the ART regimens in the past decade. In 2013, World Health Organization has released the consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV Infection, wherein, it has recommended to start treatment naïve HIV patients on fixed drug combinations of tenofovir, lamivudine and efavirenz (TLE). This regimen has been found to be safer, with fewer adverse events and has a better virological and treatment response compared with the other non-nucleoside reverse transcriptase inhibitor (NNRTI) based once- or twice-daily regimens. It has also been shown that there is no increased risk of birth defects with efavirenz as compared with other anti-retroviral drugs used during the first trimester of pregnancy [22]. The regimen is formulated as a single tablet regimen to be taken once daily. This has been strategized to improve the acceptance and compliance in PLHA population. TLE was introduced in India as the first line regimen in 2014. TLE has thus replaced other regimens as the predominantly used ART regimen. Currently majority of our patients are on the efavirenz based regimen (61%), while 33% of our patients are still maintaining well on the nevirapine based regimens.

Our retrospective analysis has shown that the median time gap between a patient being eligible for ART and the actual initiation of treatment may have increased. The authors hypothesize that this may be due to increased availability of laboratory and radiological investigations that are used by the physicians to rule out opportunistic infections to avoid immune mediated inflammatory response syndrome (IRIS) in ART naïve individuals. This strategy may be useful in some opportunistic infections such as cryptococcal or tubercular meningitis, where delaying ART may be beneficial in reducing mortality. In most others, it is seen that same-day HIV testing and ART initiation, as compared to standard care, improves retention in care with virological suppression and decreases mortality [23]. In a study from Gujarat, India by Chawla et al., high patient numbers, shortages in drug supply and social/financial issues of the patient were identified as some of the reasons for non-initiation of ART despite eligibility [24]. It needs to be emphasized in the programme, except in certain circumstances (*e.g.*, suspicion of tubercular or cryptococcal meningitis), early initiation of ART is encouraged. One should smartly weigh the risks of a possible immune reconstitution on initiation of therapy versus risk of infection with the opportunistic pathogens in case of non-initiation.

A significant proportion of the patients could not be initiated on ART due to the eligibility cut-offs at the time of their diagnosis. A major portion of these patients were transferred out as ours being an apex center, a lot of patients come here for diagnosis and return to their home state for treatment. Of the 5896 patients, who were "ART" registered, 627 (11%) patients were lost to follow up and the mortality was 10%. Similar high rates of loss to follow up in Indian patients have been found from other parts of the country as well. In a study by Alvarez-Uria et al. (2013) in Andhra Pradesh, South India, the percentage of patients lost to follow up was 10.6% [25]. In a study of loss to follow up (LTFU) among HIV-infected adolescents receiving antiretroviral therapy in Pune, India, the cumulative LTFU incidence increased from 6% to 15% over 6 years [26]. Similar high rates of loss to follow up was also seen in HIV affected pediatric population in Tamil Nadu (22%) [27]. Such high rates of loss to follow up may be due to imperfectness of counselling services, poor awareness and education of the patients and poor accessibility to ART services. However, the silver lining in the cloud in our study was the fact that the adverse outcomes including death and loss to follow up were on a declining trend. This indicates the fact that the well timed changes in the program are creating a positive impact in the outcomes of the patient.

CONCLUSION

India under the aegis of NACO has come a long way in the care of patients with HIV/AIDS. Treatment is now offered for all HIV patients free of cost irrespective of their CD4 count. The patient friendly fixed drug combination single pill (TLE) is the initial treatment for all HIV patients under the program. There has been substantial reduction in the adverse outcomes and the baseline CD4 count has also improved over the years. However, there is a need for continued reinforcement of the programmatic interventions to further reduce the

maternal to child transmission. Prospective studies are required to evaluate the reasons for delayed initiation of ART in naïve individuals taking baseline CD4 and concurrent opportunistic infections in account. There is a need to continue our fight against the menace of HIV infection in India.

Conflicts of interests
None.

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