Original Article

A Study on Clinical Profile and The Response to Antiretroviral Therapy in Pediatric HIV Patients at Tertiary Care Centre.

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ABSTRACT

Background: Human Immunodeficiency Virus (HIV) infection continues to pose major public health challenges worldwide, particularly among children. Antiretroviral therapy (ART) has markedly enhanced survival and well-being in this population; nevertheless, issues such as opportunistic infections (OIs), treatment adherence, and chronic undernutrition remain problematic. This study investigated the clinical presentation and treatment outcomes of pediatric HIV patients receiving ART at a tertiary care facility.

Methods: A prospective observational study was conducted between July 2023 and December 2024 among 100 HIV-infected children aged 18 months to 12 years at the Government General Hospital, Kakinada. Clinical manifestations, frequency of OIs, adherence patterns (via caregiver reports and pill counts), and ART response were assessed using serial CD4 measurements and viral load testing.

Results: Nearly all children (99%) acquired HIV through mother-to-child transmission. Most (62%) initiated ART within one month of diagnosis. Fever (45%) and failure to thrive (40%) were the most common presenting symptoms. Significant immunological improvement was observed, with median CD4 counts rising from 236.1 to 692.5 cells/μL at one year. Virological suppression was achieved in 84.7% of the cohort. While 77% remained on first-line regimens, 23% required a switch, primarily due to treatment failure. Despite improvements in weight and wasting indices, chronic stunting persisted in 42.4% of children after one year.

Conclusion: ART yielded strong immunological and virological benefits in children; however, persistent stunting and suboptimal adherence in one-fifth of the cohort highlight the need for intensified nutritional and psychosocial support strategies to optimize long-term outcomes.

Keywords: *Antiretroviral therapy, Pediatrics, First-line, Treatment outcome, Viral load.*

INTRODUCTION

Human Immunodeficiency Virus (HIV) continues to impose significant global health challenges, with children constituting one of the most vulnerable affected populations. Pediatric HIV infection presents with a broad clinical spectrum, ranging from asymptomatic disease to severe opportunistic infections, progressive immunosuppression, and substantial growth and developmental delays. The widespread availability of antiretroviral therapy (ART) has profoundly transformed the prognosis for these children, markedly improving survival and overall quality of life. Despite these advances, an estimated 1.7 million children under 15 years of age were living with HIV globally in 2021, the majority residing in low- and middle-income countries where access to timely diagnosis and sustained treatment remains uneven. [1]

Persistent challenges include late presentation to care, limited availability of pediatric-friendly drug formulations, adherence difficulties shaped by both child- and caregiver-related factors, and the complexities of long-term monitoring in

growing children. Mother-to-child transmission continues to be the predominant mode of pediatric HIV acquisition, highlighting the critical importance of early testing, prompt linkage to care, and initiation of ART during infancy [2,3]. In this context, evaluating the clinical manifestations, burden of opportunistic infections, treatment regimens employed, and subsequent immunological and virological outcomes in specific healthcare settings is essential for optimizing pediatric HIV management. The present study therefore aimed to characterize the clinical profile of children living with HIV and assess their response to ART, with particular emphasis on changes in CD4 count and viral load, the incidence of opportunistic infections, patterns of adherence, and the occurrence of any treatment-related adverse effects.

METHODOLOGY

This prospective observational study was conducted from July 2023 to December 2024 at the Government General Hospital, Kakinada, and included 100 HIV-positive children aged 18 months to 12 years attending the pediatric outpatient department, inpatient wards, and the ART centre. Children younger than 18 months were excluded because of diagnostic limitations. Written informed consent was obtained from parents or caregivers prior to enrolment.

Data were collected using a structured proforma following consent. Demographic characteristics, presenting symptoms such as fever, weight loss, recurrent respiratory infections, diarrhea, generalized lymphadenopathy, mucocutaneous lesions, and neurological complaints were recorded. Physical examination findings were documented to assess nutritional status and detect opportunistic infections. Details on the date of ART initiation and the regimen prescribed were also obtained.

Participants were followed longitudinally to evaluate treatment response. Immunological status was assessed through serial CD4 counts, while virological response was measured using viral load testing. Nutritional status was monitored through anthropometric indices, including weight-for-age, height-for-age, and BMI Z-scores. Adherence to ART was evaluated using pill counts and caregiver reports. All adverse drug reactions and reasons for ART regimen modification were systematically documented. Baseline laboratory investigations, including complete blood count, liver and renal function tests, and serum electrolytes, were performed to assess overall health.

Data analysis was conducted using SPSS version 26.0. Categorical variables were analysed using the chi-square test, and continuous variables using the Student's t-test. Ethical approval for the study was granted by the Institutional Ethics Committee of Rangaraya Medical College, Kakinada.

RESULTS

The present study describes the clinical profile and response to antiretroviral therapy (ART) in pediatric HIV patients. The study enrolled 100 HIV-positive children aged 18 months to 12 years. The findings reveal significant trends in CD4 count improvement, reduced viral load, and highlight factors influencing treatment success, such as adherence and nutritional status.

Table 1. Demographic Characteristics and ART Initiation (N = 100)

Characteristic	Category	Frequency (n)	Percentage
Age Distribution	2–5 Years	17	17.0%
	6–10 Years	29	29.0%
	11–12 Years	54	54.0%
Gender Distribution	Male	53	53.0%
	Female	47	47.0%
Age at Diagnosis	<2 Years	16	16.0%
	2–5 Years	52	52.0%
	6–10 Years	36	36.0%
	11–12 Years	7	7.0%
Mode of Transmission	Mother to Child	99	99.0%
	Probably due to Blood Transfusion	1	1.0%
Time to ART Initiation	<1 Month	62	62.0%
	1–12 Months	10	10.0%
	1–3 Years	15	15.0%
	3–5 Years	6	6.0%
	>5 Years	7	7.0%

The demographic analysis showed that the majority of participants were aged 11–12 years (54%), followed by the 6–10 years group (29%). Males slightly outnumbered females (53% vs. 47%). Most children were diagnosed between 2–5 years of age (52%). Mother-to-child transmission (MTCT) was the overwhelming mode of HIV acquisition (99%). A majority of patients (62%) were started on ART within 1 month of diagnosis.

Table 2. Clinical Features at Diagnosis (N = 100)

Clinical Feature	Frequency (n)	Percentage (%)
Fever	45	45.0%
Failure to Thrive	40	40.0%
Generalized Lymphadenopathy	35	35.0%
Chronic Diarrhoea	30	30.0%
Skin Infections (Fungal/Bacterial)	28	28.0%
Persistent Cough	25	25.0%
Severe Malnutrition	25	25.0%
Oral Thrush	20	20.0%
Hepatosplenomegaly	18	18.0%
Pneumonia	15	15.0%
Neurological Symptoms	10	10.0%

Fever (45%) was the most common clinical manifestation observed at diagnosis, followed by failure to thrive (40%). Generalized lymphadenopathy (35%) and chronic diarrhea (30%) were also highly prevalent. According to the WHO Pediatric Clinical Staging at the time of diagnosis, 32% of patients presented with moderate symptoms (Stage 3), 28% had mild symptoms (Stage 2), 25% were asymptomatic (Stage 1), and 15% had severe disease (Stage 4).

Table 3. Opportunistic Infections (N = 100)

Opportunistic Infection	Frequency (n)	Percentage (%)
Chronic Diarrhea	30	30%
Skin Infections (Fungal, Bacterial)	28	28%
Oral Candidiasis	20	20%
Bacterial Pneumonia	15	15%
Tuberculosis (TB)	2	2%

The most common opportunistic infections (OIs) observed were chronic diarrhea (30%) and skin infections (28%). Oral candidiasis was present in 20% of children, and bacterial pneumonia in 15%. Notably, only 2% of patients were diagnosed with pulmonary tuberculosis (TB), with no cases of extra-pulmonary TB reported.

Table 4. Antiretroviral Therapy Characteristics (N = 100)

Characteristic	Category	Frequency (n, %)
Line of Treatment	1st Line	77 (77.0%)
	2nd Line	23 (23.0%)
Present ARV Drug Regimen	A-TLD (Tenofovir + Lamivudine + Dolutegravir)	37 (37.0%)
	P-AL+D (Abacavir/Zidovudine + Lamivudine + Dolutegravir)	31 (31.0%)
	A-AL+D (Abacavir + Lamivudine + Dolutegravir)	18 (18.0%)
	A-ZL+D (Zidovudine + Lamivudine + Dolutegravir)	8 (8.0%)
	P-AL+LPV/r (Abacavir + Lamivudine + Lopinavir/Ritonavir)	6 (6.0%)
Medication Adherence	Good (>95%)	47 (47.0%)
	Average (80–95%)	33 (33.0%)
	Poor (<80%)	20 (20.0%)

First-line ART was used by 77% of children, while 23 children were switched to second-line ART due to side effects or lack of response. The most common present regimen was A-TLD (37%), reflecting a preference for Dolutegravir-containing regimens. Adherence to ART was assessed as good (>95%) in 47% of participants, with 20% showing poor adherence (<80%).

Table 5. Immunological and Virological Response to ART

Parameter	Baseline (n=100)	6 months (n=88)	1 year (n=85)
Virological Response			
Median viral load (copies/mL)	28,815 (1871-48,023)	1,820 (0-21,486)	0 (0-606)
Nil (Undetectable) Viral Load	-	48 (54.5%)	72 (84.7%)
CD4 Count (Mean ± SD)			
1st Line Regimen	910.25 ± 720.30	1025.40 ± 435.60	1120.85 ± 410.25
2nd Line Regimen	750.60 ± 765.15	920.75 ± 415.80	980.45 ± 400.35

A significant decline in viral load was observed over the study period, demonstrating effective suppression by ART. The median baseline viral load was 28,815 copies/mL, dropping to an undetectable level (0 copies/mL) at 1 year in most patients. Undetectable viral load was achieved in 84.7% of patients at 1 year.

The mean CD4 count for patients maintained on first-line ART increased steadily, starting at 910.25 ± 720.30 at baseline and reaching 1120.85 ± 410.25 after 1 year. Among the 77 children who continued on the first line regimen, 77.9% achieved a normal CD4 count ($\geq$500 cells/μL) by the end of the study.

Nutritional Status and Growth Parameters

The nutritional status of the pediatric HIV patients at enrollment was concerning, with mean Z-scores indicating moderate undernutrition and stunting. The mean Weight for Age Z-score (WAZ) was -1.92, the mean Height for Age Z-score (HAZ) was -1.97, and the mean BMI Z-score (BAZ) was -1.11.

At baseline, 40% of children had normal weight-for-age, while 25% had severe undernutrition (WAZ < -3SD). Similarly, 25% exhibited severe stunting (HAZ < -3SD).

Over the one-year study period, improvements in nutritional status were noted. The median WAZ improved from -1.92 at baseline to -1.34 at 1 year, and the percentage of underweight children (WAZ <-2SD) decreased from 42.4% to 28.3%. Wasting (WHZ <-2SD) reduced significantly from 28.3% at baseline to 0.1% at 1 year, suggesting nutritional recovery. However, the median HAZ only slightly improved (-1.97 to -1.75), with 42.4% of children remaining stunted (HAZ <-2SD) after one year, indicating persistent chronic undernutrition.

ART Regimen Switches and Adverse Reactions

Of the 100 children initially started on first-line ART, 23 were subsequently switched to second-line therapy. The primary reason for switching to a second-line regimen was treatment failure (73.9%), while the remaining 26.1% switched due to drug toxicity or side effects.

Adverse drug reactions (ADRs) varied depending on the specific regimen used. Patients on the A-ZL+D (Zidovudine-based) regimen experienced the highest incidence of anemia (37.5%), along with fatigue and nausea. For patients on P-AL+LPV/r, metabolic disorders and diarrhea (33.3% each) were the most common issues, alongside hepatotoxicity (16.7%) and hyperlipidemia (16.7%). Deranged renal function (increased serum creatinine) was noted in 13.5% of patients on A-TLD.

Adherence Challenges and Tuberculosis Prevention

Among the 53 participants demonstrating suboptimal ART adherence (average or poor adherence), the most common factor leading to non-compliance was child refusal to take medication (39.6%), followed by forgetfulness by the child or caregiver (22.6%). Other barriers included fear of stigma and discrimination (15.1%), medication side effects (13.2%), and caregiver unavailability (9.4%).

Concerning tuberculosis prevention, 74% of pediatric HIV patients successfully completed Isoniazid Preventive Therapy (IPT), while 26% were still receiving IPT at the time of evaluation. Only 2% of the cohort was diagnosed with pulmonary TB.

DISCUSSION

This study provides an in-depth evaluation of clinical profiles and ART outcomes among HIV-infected children, offering evidence of substantial immunological recovery and virological suppression, while highlighting persistent issues related to malnutrition and adherence.

Age Distribution

A considerable proportion of participants were in the older pediatric age group (11–12 years), mirroring the demographic patterns described by Chandrasekaran et al. [4], who similarly reported a predominance of school-aged children in treatment cohorts. Other investigators have documented younger populations, such as Mir et al. [5], who observed a median ART initiation age near six years, this could be due to better implementation of PPTCT program reducing the mother to child transmission.

Gender Distribution

The near-equal distribution of males (53%) and females (47%) aligns with observations from Chandrasekaran et al. [4] and Prasad et al. Studies by Mir et al. [5], Gomber et al. [6] reported a more pronounced male predominance, likely reflecting regional care-seeking patterns or demographic variations.

Anthropometric Trends

Baseline anthropometry revealed widespread undernutrition, with reduced WAZ, HAZ, and BMI Z-scores. Improvements after one year of ART—including reductions in underweight and wasting—echo findings from Chandrasekaran et al. [4], who noted sustained nutritional recovery over 24 months. Mir et al. [5] similarly reported substantial normalization of WAZ scores over time. Nonetheless, persistent stunting in our cohort reflects chronic nutritional deficits and underscores the need for dietary interventions integrated with ART programs.

Clinical Manifestations

Fever, failure to thrive, chronic diarrhea, and lymphadenopathy were common presenting features, consistent with reports from Prasad et al. [7]. Our staging distribution, with nearly one-third in WHO Stage 3 and 15% in Stage 4, differs from Rajput et al. [8], who observed predominantly mild disease at diagnosis, indicating possible differences in timing of presentation and diagnostic access.

Opportunistic Infections

Chronic diarrhea and skin infections were the most frequent OIs, whereas TB prevalence (2%) was notably low. This contrasts with studies by Gomber et al. [6], where TB was the predominant OI. High IPT completion rates in our cohort may partially explain the lower TB incidence, alongside improved TB screening and preventive strategies.

Transmission

MTCT accounted for nearly all infections, paralleling findings from Kumar et al., Gomber et al., and Prasad et al. Such consistently high vertical transmission rates emphasize the continuing need to strengthen PMTCT programs and early maternal testing.

Antiretroviral Therapy Patterns

Most children remained on first-line therapy; however, nearly one-quarter required regimen modification, primarily due to treatment failure. The substantial use of Dolutegravir-based regimens aligns with current national and global recommendations. Earlier studies, such as those of Chandrasekaran et al. [4] and Prasad et al., relied heavily on Nevirapine or Zidovudine-based combinations, which were more frequently associated with toxicities and resistance.

Immunological and Virological Outcomes

The marked rise in CD4 counts and the achievement of viral suppression (84.7% at one year) demonstrate effective ART response. Similar trends have been documented by Mir et al. [5] and Chandrasekaran et al. [4], although rates of virological failure in NNRTI-based regimens were historically higher. Persistent low CD4 counts in a subset of our cohort highlight the need for continued monitoring and tailored interventions.

Adherence Challenges

Adherence remained suboptimal for 20% of participants, with child refusal and caregiver forgetfulness being major barriers. These findings contrast with higher adherence levels reported by Rajput et al. [8] and underline the importance of adherence counseling, caregiver education, and child-friendly ART formulations.

CONCLUSION

Antiretroviral therapy demonstrated significant benefits in pediatric HIV care, with clear improvements in immune recovery and effective viral suppression among treated children. Despite these positive clinical outcomes, persistent stunting indicates unresolved nutritional deficits, and adherence challenges remain a major barrier to optimal long-term management. These findings emphasize the need for a comprehensive care model that integrates nutritional support, active caregiver involvement, and structured adherence-enhancing interventions alongside ART. Additionally, the lower proportion of HIV-positive children in younger age groups reflects the effective implementation of Prevention of Parent-to-Child Transmission programs, highlighting their success in reducing vertical transmission and improving early childhood HIV control.

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