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Antiretroviral treatment and immune recovery outcomes in patient health-related quality of life

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Abstract:
HIV or AIDS patients' subjective health-related quality of life is an important patient-centered metric for assessing antiretroviral therapy's clinical efficacy. Therefore, it is of interest to examine the short-term effects of continuous pharmacological therapy on immunological recovery and multidimensional functional wellbeing in 152 adult patients admitted to an Indian tertiary care setting. The first treatment phase increased median CD4 counts from 304 to 439 cells/mm^3, with large and statistically significant changes in all physical, psychological and environmental domains. These findings show a clear link between early immunological reconstitution and patient well-being and support the routine clinical use of standardized patient-reported outcome measures.

Keywords: Antiretroviral therapy (ART), CD4 dynamics, health-related quality of life

Background:
HIV infection disrupts physical and social autonomy for millions of people worldwide, despite abundant access to modern therapeutic advances **[1].** In addition to systemic virological suppression, subjective evaluation of physical, psychological and environmental wellbeing is a key metric for HIV management **[2].** The severe psychological and physical deterioration of vulnerable patients in developing demographic settings like India is always worsened by the disease's profound socioeconomic burdens **[3].** In addition to immunological stability, societal stigma and internalized psychological distress independently lower total subjective quality of life scores **[4].** Untreated clinical depression often occurs with active HIV infection, increasing the physiological burden and reducing daily independence **[5].** Systemic psychosocial barriers still prevent resource limited clinical settings from adherence to life-saving antiretroviral therapies, according to extensive community based epidemiological research **[4].** Global implementation of highly active antiretroviral therapy has transformed HIV from a fatal disease into a manageable chronic infectious disease. Long-term immunological recovery depends on strict adherence to daily drug regimens **[6].** By increasing absolute CD4 lymphocyte counts, rapid systemic immune reconstitution restores host physiologic integrity and reduces devastating opportunistic infections. Previous epidemiological studies have shown a strong, positive correlation between CD4 strata and self-reported QoL **[7].** Early proactive pharmacological initiation and sustained clinical retention improve subjective patient wellness scores significantly over time, according to extensive therapeutic validation studies **[8].** The World Health Organization Quality of Life-HIV BREF (WHOQOL-HIV BREF) is locally validated and captures complex, interconnected functional improvements across physical, psychological and spiritual domains **[2].** In complex tertiary care centers in India, cross-sectional studies show that educational and socioeconomic stability speed psychosocial recovery **[9].** Fast immunological recovery also protects vulnerable systemic neurocognitive pathways, boosting psychological resilience **[5].** This prospective, structured study quantifies the immediate short-term relationship between early, antiretroviral-driven CD4 recovery and rapid, multidimensional HR-QoL improvements in a localized clinical cohort **[10].** Therefore, it is of interest to evaluate the rapid antiretroviral-driven CD4 recovery relates to immediate improvements in physical, psychological and environmental domains of quality of life in adult HIV or AIDS patients.

Materials and Methods:
Study design and setting:
This was a prospective observational study conducted at a tertiary antiretroviral therapy (ART) center.

Study period:
Data collection included a well-defined, prospective follow-up period with complete baseline enrollment and systematic patient reassessment exactly 90 days after ART initiation or continuation.

Patient demographics:
A total of 152 adult patients with confirmed HIV/AIDS were enrolled. Study population: 87 males (57.20%) and 65 females (42.80%). The majority of the study population (76.97%, n=117) were ≤ 40 years of age. The majority of the participants, 80.26% (n=122), had an educational level of high school or less. The predominant route of transmission was sexual in 73.00% (n=111) of cases. 39.50% (n=60) of the cohort reported active alcohol consumption. At baseline, 29.28% of evaluated patients had severely depleted CD4 counts (<200 cells/mm3).

Inclusion and exclusion criteria:
Inclusion criteria included adult patients (>18 years) with a confirmed diagnosis of HIV/AIDS attending the ART center, who were willing to provide formal informed consent and complete the baseline and follow-up assessments. Patients were excluded if they had severe cognitive impairment, were critically ill at the time of the interview (and therefore unable to complete the questionnaire), or were unwilling to sign a written consent form. Variables Studied Main variables considered were baseline clinico-demographic characteristics, categorization of baseline absolute CD4 counts and their respective WHOQOL-HIV BREF

domain scores (Physical, Psychological, Level of Independence, Social Relationship, Environment and Spirituality or Religion or Personal Beliefs (SRPB)). General health perception measures were also assessed at baseline and the 90-day follow-up interval.

Statistical methods:
Categorical variables were described by frequencies and percentages. The baseline WHOQOL-HIV domain scores were compared across the stratified CD4 categories using a one-way ANOVA. Longitudinal comparisons of absolute CD4 counts from baseline to follow-up were made using the non-parametric Wilcoxon signed-rank test to account for heavily skewed physiological distribution. Paired t-tests were conducted to evaluate baseline to follow-up changes in all six WHOQOL-HIV domains and General Health Perception scores. Calculated p-value of <0.05 was considered statistically significant.

Ethics approval status:
The study protocol was formally approved by the Institutional Ethics Committee. All participants enrolled provided written informed consent before data were systematically collected.

Table 1: Aggregated baseline clinico-demographic profile (n=152)

Variable (Category 1 / Category 2)	Frequency (N)	Percentage (%)
Gender (Male / Female)	87 / 65	57.20 / 42.80
Age Group (≤ 40 Years / > 40 Years)	117 / 35	76.97 / 23.03
Education Status (Up to High School / Higher Education)	122 / 30	80.26 / 19.74
Primary Transmission (Sexual / Non-Sexual or Unknown)	111 / 41	73.00 / 27.00
Alcohol Consumption (Active Consumer / Non-Consumer)	60 / 92	39.50 / 60.50
Baseline CD4 Count* (<200 / 201–500 / >500)	41 / 58 / 41	29.28 / 41.44 / 29.28

**Note: Baseline CD4 Count (N=140); cells/mm³*

Table 2: Comparison of HR-QOL Domain Scores by CD4 count category at baseline

WHOQOL-HIV Domain	<200 cells/mm³(n=41)	201–500 cells/mm³(n=58)	>500 cells/mm³(n=41)	ANOVAp-value
Physical	13.60 ± 2.96	14.25 ± 2.62	15.06 ± 2.97	0.071
Psychological	12.94 ± 2.21	13.63 ± 1.95	14.02 ± 2.03	0.060
Level of Independence	13.57 ± 3.38	14.87 ± 2.71	15.35 ± 2.76	**0.019**
Social Relationship	13.46 ± 1.89	13.75 ± 2.01	14.28 ± 1.61	0.135
Environment	13.34 ± 1.30	13.80 ± 1.42	13.87 ± 1.56	0.179
SRPB*	14.59 ± 2.40	14.70 ± 2.03	14.77 ± 1.90	0.924

**Significant at p < 0.05. SRPB: Spirituality, Religion and Personal Beliefs.*

Table 3: Impact of antiretroviral therapy (ART) on CD4 count and HR-QOL domains (Baseline vs. 90-Day Follow-up)

Parameter	Baseline Score	90-Day Follow-up	p-value
Immunological Status			
Median CD4 Count (N=86)	304	439	<0.001†
WHOQOL-HIV Domains (N=122)			
Physical	14.13 ± 2.89	17.12 ± 1.31	<0.001‡
Psychological	13.50 ± 2.11	16.07 ± 1.61	<0.001‡
Level of Independence	14.58 ± 3.00	15.38 ± 1.55	0.002‡
Social Relationship	13.81 ± 1.89	14.65 ± 1.67	<0.001‡
Environment	13.75 ± 1.43	14.93 ± 1.68	<0.001‡
SRPB	14.61 ± 2.18	15.23 ± 1.49	<0.001‡
General Health Perception	3.22 ± 0.88	4.13 ± 0.44	<0.001‡

†Calculated using Wilcoxon signed-rank test. ‡Calculated using Paired t-test.

Results and Discussion:
The cohort's baseline socio-demographic profile **(Table 1)** was predominantly younger (76.97% aged ≤ 40 years) with limited educational attainment (80.26% completing up to high school) representing the vulnerable sector that was disproportionally exposed to the socioeconomic burden of chronic illness. Major mode of exposure was sexual (73.00%) and 29.28% of patient presented with advanced immunosuppression (CD4 < 200 cells/mm³) prior the initiation of therapy **[11]**. Continuous ART afforded simultaneous immunological and functional benefits over the 90-day operational observation period. Among participants who remained in the study, the median absolute CD4 count significantly increased from 304 to 439 cells/mm³ ($p < 0.001$; **Table 3**) confirming that ART adherence drives immune recovery trajectories **[12]**. Improvements were noted in the scores in all the domains of the WHOQOL-HIV BREF instrument, which were statistically significant ($p < 0.005$). The greatest absolute gains were in the Physical (14.13 ± 2.89 to 17.12 ± 1.31) and Psychological (13.50 ± 2.11 to 16.07 ± 1.61) domains. Our findings are consistent with larger cohorts globally and meta-analyses which have reported that early pharmacologically induced immune reconstitution is an immediate driver of self-reported functional recovery **[8, 13]**. A positive gradient between subjective quality-of-life scores and absolute CD4 strata was observed at baseline evaluation. The association between the Level of Independence domain and absolute CD4 strata was statistically significant (p=0.019; **Table 2**). According to Jain *et al.* **[7],** the observed trend corroborates multicenter results and Chandra *et al.* **[5]** also noted improvement in the neuro-immunological structure which helps in reservation of immunological competence to preserve daily autonomy, physical mobility and vocational capacity. Moreover, the control of common comorbidities (hypertension) during ART also promotes sustained physical independence **[14].** In contrast, the

study found no significant difference in baseline scores for the Environment (p = 0.179) and Social Relationships (p = 0.135) domains across the CD4 strata. According to Kohli *et al.* **[3],** the current upper bound for social and environmental scores arising from systemic poverty, lack of infrastructure and social stigma, is unrelated to baseline lymphocyte counts. The advancement in the Physical and Psychological domain by 90 days was swifter than the slow change in longer longitudinal studies **[15].** Physiological restoration helps reduce somatic symptom burden and improve general health perception (3.22 ± 0.88 to 4.13 ± 0.44, ps < 0.001), however, longitudinal trajectory studies have shown that psychosocial barriers remain **[10, 16 and 17]**. In independent research Charles *et al.* **[4]** and Akoko *et al.* **[18]** the internalisation of stigma and untreated depression have a dampening effect on mental well-being independent of either virological suppression or switching of clinical regimen **[19]**. Recent studies by Hong *et al.* **[20]** and Mantri *et al.* **[21]** found that adherence to medication is one of those factors that cannot be denied in viral suppression and cell proliferation **[6].** However, pharmacotherapy combined with regular psychosocial counselling and organized measures to address structural impediments are essential for sustained and comprehensive health-related quality of life **[22].** We have to mention a number of methodological issues. This 90-day follow-up period, along with a real-life replication of the TRANSCEND trial; provide a good balance of opportunity for acute reconstitution dynamics. However, we do not assess long-term social reintegration and treatment fatigue. Moreover, there was modest attrition in paired analytical sub-samples due to loss to follow-up. Ultimately, one additional limitation of our study is the single-center design. According to research, future multicenter studies (including larger and lower-income patient pools) will have to implement longer follow-up horizons and multivariable modelling to validate the supposed relationship between immunologic recovery, depressive symptoms and socio-economic status **[9].**

Conclusion:

A continuous 90-day antiretroviral therapy treatment led to significant physiological CD4 recovery and multi-dimensional improvements in physical, psychological and environmental quality of life. In symptomatic patients, higher systemic immunological strata were associated with greater functional independence at baseline. Thus, these strong early recovery results strongly recommend the mandatory and universal use of structured patient-reported quality of life assessments alongside conventional laboratory monitoring protocols in infectious disease workflows.

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