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Original Article

Nonadherence to first-line antiretroviral therapy among human immunodeficiency virus-1 infected children at the Jos University Teaching Hospital, Jos, Nigeria

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Abstract

Background: Nonadherence to antiretroviral therapy (ART) may encourage the development of resistance to antiretroviral drugs (ARVs). Poor adherence is known to be associated with ART failure which could compromise the benefits of ART in children. Therefore, it is important to identify the reasons why children on ART may fail to take their ARVs. In this study, we described the characteristics of human immunodeficiency virus-1 (HIV-1) infected children with ART nonadherence as well as the reasons for their nonadherence.

Methodology: A retrospective cohort study in which data on 580 HIV-1 infected children enrolled on ART between February 2006 and December 2010 at the pediatric HIV clinic of the Jos University Teaching Hospital, Jos, was analyzed. Subjects were aged 2 months to 15 years. Information on adherence was obtained by child or caregiver self-report. They also had repeated adherence counseling during each clinic follow-up visit and were taught the use of alarm clocks daily for reminding them of when the next ARV dose will be due.

Results: There were 30 (5.2%) children with non-adherence to ART. Among children with nonadherence, majority were: Children aged 1-10 years (76.7%), males (53.3%) and did not know their diagnosis of HIV (90.9%). The odds of nonadherence was two times higher among children who failed first-line ART compared with those who did not (odds ratio [95% confidence interval], 2.28 [1.03-5.02], $P = 0.04$). The most common reason for nonadherence was: Forgot to take medications (46.7%).

Conclusion: The low rate of nonadherence to ART in this study could be attributed to repeated adherence counseling during each clinic follow-up visit and the use of alarm clocks daily for reminders on when the next ARV dose will be due.

Key words: Adherence counseling, antiretroviral therapy, human immunodeficiency virus-1, nonadherence, self-report

Introduction

Sub-Saharan Africa bears the largest burden of the human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) with an

estimated 2.9 million children living with HIV/AIDS in 2012.^[1] In 2010, it was estimated that Nigeria had about 440,000 children below the age of 15 years living with HIV/AIDS^[2] of which 280,000 were eligible for antiretroviral therapy (ART), but only 7% were receiving it.^[3] Among children who were able to get ART there usually would be those that may fail to adhere to ART. One systematic review of pediatric adherence to ART in low- and middle-income countries showed that this ranged from 49% to 100%, with 76% of the articles reporting >75% adherence.^[4]

Several factors such as socioeconomic, cultural, behavioral and clinical factors^[4-10] have been reported to be

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associated with non-adherence to ART in children. Some of these factors may be patient-related such as age, sex and ethnicity.^[11] Nonadherence to ART may encourage the development of resistance to antiretroviral drugs (ARVs).^[12] Poor adherence^[5,13,14] and drug resistance^[14,15] are known to be associated with ART failure which could compromise the benefits^[16-20] of ART in children. With more countries scaling-up ART in the West African sub-region, there is the possibility that more children will be developing ART failure due to compromised adherence. Therefore, it is important to identify the reasons why children on ART fail to take their medications. In this study, we describe the characteristics of HIV infected children with ART nonadherence as well as the reasons for their nonadherence to ART.

Methodology

Study Design

We analyzed data on a cohort of 580 HIV-1 infected children who were enrolled on ART between February 2006 and December 2010 at the AIDS Prevention Initiative in Nigeria (APIN)-supported pediatric HIV clinic of the Jos university teaching hospital (JUTH), Jos, Nigeria. The children were aged 2 months - 15 years diagnosed with HIV-1 infection at presentation to APIN, JUTH and subsequently commenced on first-line ART. Approval for this study was given by the Ethics committee of JUTH. A written informed consent was obtained from the parents/guardians of the children for use of the data for research. Prior to commencing ART, ART adherence counseling was given to the children and their caregivers. During each subsequent monthly clinic follow-up visit, a general health talk was given and the importance of ART adherence re-emphasized to the children and their caregivers. The children and their caregivers were also taught how to use alarm clocks daily for reminding them of when the next ARV dose is due.

The diagnosis of HIV and the criteria for commencement of ART in children was based on Nigeria's National Guidelines for Pediatric HIV and AIDS Treatment and Care.^[21] Children diagnosed with HIV were placed on any of the following combinations of first-line ART: Zidovudine (AZT) + lamivudine (3TC) + nevirapine (NVP) or AZT + 3TC + efavirenz (EFV); and the dosing regimen were twice a day for AZT, 3TC and NVP or once a day for EFV.^[21]

Adherence counseling was done by trained Nurses and adherence counselors all of who were trained in the early years of the APIN HIV care program, by professional adherence counselors from the Harvard School of Public Health, Boston, MA, USA.

In this study, nonadherence was defined as: Failure to take medications (missed >2 doses or missed >1 day

of ART within 30 days), resulting in an ART adherence rate of < 95%,^[22,23] which was determined during the 1-month prior to the seventh follow-up visit. Each child had a total of 7 follow-up monthly visits to the clinic over a period of 8 months since starting ARVs. The information on ART adherence and the various reasons for nonadherence were obtained by patient or caregiver self-report through direct questioning and captured in the standardized Patient Management and Monitoring (PPM) form. The PPM is the pediatric follow-up clinical encounter form that was designed by the Nigeria National Task Team on Pediatric ART and validated by the Harvard School of Public Health. Data on first-line ART failure, based on the definition of the national guidelines^[21] was also obtained.

Statistical Analysis

Children with ART nonadherence were compared with those who adhered to ART; ART non-adherence (yes/no) was regarded as the binary outcome variable. The weight-for-age z score (WAZ) was determined from their weight, adjusted for age and sex, using the WHO AnthroPlus software^[24] by importing the variables - weight, age and sex in the form of a text file into the software. Next, the WAZ was categorized into a binary variable using the WHO cut-off of $Z < -3$, with $WAZ < -3$ defined as severe malnutrition.^[25] The WHO clinical stage was stratified into stage 3/4 versus stage 1/2, while HIV RNA viral load was categorized into $<10.5 \log_{10}$ versus $\geq 10.5 \log_{10}$ copies/mL using the median cut-off value. Haemoglobin (Hb) level was also categorized into Hb <8 g/dL (anemia) and >8 g/dL.

Analyses were carried out using Stata software version 10.0 (Stata Corporation, College Station, Texas, USA). The association between baseline characteristic and the outcome was examined using the Chi-squared or Fisher's exact test for categorical variables, while the Wilcoxon-Mann-Whitney test was used for comparison of two medians. Univariate logistic regression was used to examine the association between subject's characteristics and outcome with results expressed as odds ratios (OR) with their 95% confidence intervals (CIs). The frequency and percentage of the various reasons for nonadherence to ART among the children were also determined. Statistical tests were two-sided with $P < 0.05$ considered as statistically significant.

Results

There were 30 (5.2%) children of the 580 studied that had non-adherence to ART, that is, adherence was 94.8%. Majority of the study subjects were: Aged 1-10 years (444, 76.8%), males (51.0%), did not know their diagnosis of HIV (93.2%), had caregivers who did not belong to any HIV support group (92.7%), had no oral

thrush (96.6%), where in WHO clinical stage 1/2 (58.6%), not anemic (95.2%), not severely malnourished (76.9%), did not fail first-line ART (81.2%) and had log viral load < 10.5 copies/mL (51.2%), [Table 1].

Among children with ART nonadherence, majority were: Children aged 1-10 years (76.7%), males (53.3%), did not know their diagnosis of HIV (90.9%), had log viral load < 10.5 copies/mL (59.0%), did not have oral thrush (96.7%), were not anemic (92.9%), were in WHO clinical stage 1/2 (60.0%), were not severely malnourished (64.3%). Those who failed first-line ART were 33.3%, [Table 1].

The median (interquartile range) absolute CD4 count was higher in children with nonadherence to ART compared with those who adhered: 500 (318-895) versus 476 (267-790), but this difference was not statistically significant ($P = 0.58$). The odds of nonadherence was two times higher among children who failed first-line ART compared with those who did not (OR [95% CI], 2.28 [1.03-5.02], $P = 0.04$), [Table 1].

The most common reason for nonadherence among the 30 children with ART nonadherence was: Forgot to take medications (46.7%), and this was followed by ran out of medicine as the next common reason (20%), [Table 2].

Discussion

Our study showed a nonadherence rate of 5.2% which was lower than the 58% obtained in a study of ART adherence among Togolese children.^[10] One systematic review of adherence study in developing countries, estimates adherence levels to range between 49% and 100%.^[4] Our lower figure for nonadherence (5.2%), that is, a relatively high figure for adherence (94.8%) may be due to the repeated adherence counseling that the children and their caregivers received during follow-up visits. We determined nonadherence at the seventh follow-up visit. Another possible explanation for our observed low level of non-adherence may be because majority of our study subjects were younger children < 10 years of age (89.4%); and studies have shown that nonadherence levels increase with increasing age in HIV-infected children,^[26-28] with the problem worse in adolescents.

Although the frequency of nonadherence was higher in males (53.3%) than females (46.7%) in our study, this difference was not statistically significant ($P = 0.78$). This was in contrast to the finding in other studies that female gender was associated with nonadherence.^[10,27] Our observation should be expected as the gender of the child should not have any impact on adherence since it is the responsibility of the parents/caregivers to give medications to their children.

Though majority of the children with nonadherence (76.7%) were children aged 1-10 years,

Table 1: Baseline characteristics of all HIV-1 infected children and those with nonadherence to ART

| Characteristics | Total n (%) | ART nonadherence n (%) | | P value* |
|---|------------------------|------------------------|------------------------|----------|
| | | Yes | No | |
| All subjects | 580 (100) | 30 (5.2) | 550 (94.8) | |
| Age (years) | | | | |
| <1 | 73 (12.6) | 5 (16.7) | 68 (12.4) | 0.83 |
| 1-5 | 297 (51.4) | 15 (50.0) | 243 (52.7) | |
| 6-10 | 147 (25.4) | 8 (26.7) | 139 (25.4) | |
| >10 | 61 (10.6) | 2 (6.6) | 59 (10.7) | |
| Median (IQR) | 3.5 (1.8-6.6) | 3.2 (1.6-5.5) | 3.5 (1.8-6.7) | 0.40** |
| Sex | | | | |
| Male | 295 (51.0) | 16 (53.3) | 279 (50.7) | 0.78 |
| Female | 285 (49.0) | 14 (46.7) | 271 (49.3) | |
| Child knows diagnosis of HIV | | | | |
| Yes | 18 (6.8) | 1 (9.1) | 17 (6.7) | 0.76 |
| No | 246 (93.2) | 10 (90.9) | 236 (93.3) | |
| Caregiver is member of support group | | | | |
| Yes | 40 (7.3) | 2 (6.7) | 38 (7.4) | 1.00 |
| No | 505 (92.7) | 28 (93.3) | 477 (92.6) | |
| Oral thrush | | | | |
| Present | 20 (3.4) | 1 (3.3) | 19 (3.5) | 1.00 |
| Absent | 559 (96.6) | 29 (96.7) | 530 (96.5) | |
| WHO clinical stage | | | | |
| 1/2 | 335 (58.6) | 18 (60.0) | 317 (58.5) | 0.87 |
| 3/4 | 237 (41.4) | 12 (40.0) | 225 (41.5) | |
| Hemoglobin level | | | | |
| <8 g/dL | 26 (4.8) | 2 (7.1) | 24 (4.7) | 0.64 |
| ≥8 g/dL | 513 (95.2) | 26 (92.9) | 487 (95.3) | |
| Median (IQR) | 10 (9-11) | 10.0 (9.5-11.0) | 10 (9-11) | 0.70** |
| WAZ | | | | |
| ≤-3 | 120 (23.1) | 10 (35.7) | 110 (22.4) | 1.00 |
| >-3 | 400 (76.9) | 18 (64.3) | 382 (77.6) | |
| Median (IQR) | -1.8 (-2.9 - -0.8) | -2.1 (-3.4 - -0.8) | -1.8 (-2.8 - -0.8) | 0.65** |
| Failed first-line ART† | | | | |
| Yes | 109 (18.8) | 10 (33.3) | 99 (18.0) | 0.04 |
| No | 471 (81.2) | 20 (66.7) | 451 (82.0) | |
| Absolute CD4 count (per mm ³) | | | | |
| Median (IQR) | 478 (267-794) | 500 (318-895) | 476 (267-790) | 0.58** |
| Percentage CD4 count | | | | |
| Median (IQR) | 17 (11-25) | 18 (13-26) | 17 (11-25) | 0.33** |
| HIV RNA viral load (copies/ml) | | | | |
| Median (IQR) | 38597 (4145-170133) | 53018 (3873-127141) | 38075 (4145-170805) | 0.31** |
| HIV RNA log viral load (copies/ml) | | | | |
| <10.5 | 191 (51.2) | 13 (59.0) | 178 (50.7) | 0.45 |
| ≥10.5 | 182 (48.8) | 9 (41.0) | 173 (49.3) | |
| Median (IQR) | 10.6 (8.3-12.0) | 10.0 (7.9-12.0) | 10.7 (8.6-12.1) | 0.31** |

*P value for Chi-squared or Fisher's exact test for the association between categorical variables and treatment failure, **P value Wilcoxon rank sum test for comparison of two medians, †This is a nonbaseline characteristic. WAZ - Weight-for-age Z score, IQR - Interquartile range, ART - Antiretroviral therapy, RNA - Ribonucleic acid, HIV - Human immunodeficiency virus

Table 2: Reasons for nonadherence to ART in HIV-1 infected children

| Reasons for ART nonadherence | Number of children | Percentage |
|----------------------------------|--------------------|------------|
| Felt good | 0 | 0 |
| Forgot/slept through | 14 | 46.7 |
| Can't adhere to schedule | 0 | 0 |
| Patient refused to take medicine | 2 | 6.7 |
| Stigma of HIV/AIDS | 0 | 0 |
| Physician instruction | 0 | 0 |
| Never returned | 4 | 13.3 |
| Ran out of medicine* | 6 | 20 |
| Patient moved | 0 | 0 |
| Toxicity | 0 | 0.9 |
| Drug interaction | 0 | 0 |
| Medicine not available | 0 | 3.6 |
| Not able to pay | 0 | 0 |
| Caregiver travelled | 2 | 6.7 |
| Others | 2 | 6.6 |
| Total | 110 | 100 |

*Children who ran out of medicine did so, not because medicines were not available, but because they failed to keep their appointment dates. ART - Antiretroviral therapy, HIV - Human immunodeficiency virus, AIDS - Acquired immunodeficiency syndrome

this does not suggest that the problem is more in this age group in our study because this same age group constitutes the majority (76.8%) of the entire study population.

In our study, majority of the children with nonadherence did not know their diagnosis of HIV (from lack of full parental disclosure). This observation is in conformity with studies which showed that motivation for a better adherence was enhanced by complete parental disclosure to the child, of the child's HIV diagnosis.^[29,30] Our finding may be explained by the fact that majority of our study children were under 5 years (66.7%), which is below the commonly accepted age of 6 years at which to start parental disclosure.^[31] Thus, as a result of this cut-off age for parental disclosure, frequent adherence counseling for children below this age would not have had much impact on the awareness of their own HIV status. Moreover, it is the responsibility of parents/guardians to disclose a child's HIV status to him/her. Despite the recommendation that disclosure should start from 6 years of age,^[31] many parents are reluctant to disclose to their children. Some of the reasons they give is that the child will not understand, or that the child may tell his friends, playmates and teachers leading to stigmatization. Another reason is that of the feeling of guilt on the part of the parents. Due to all these reasons, in our pediatric HIV clinic we encourage children to take their medications regularly without telling them specifically why they are taking the medications, if parents/guardians were yet to disclose the children's status to them.

Majority of the children in our study with nonadherence were in WHO clinical stage 1/2 (less advanced HIV) which was in contrast to a previous study^[32] which showed that adherence increases in children with more advanced HIV (WHO clinical stage 3/4). The increase in adherence

in children with advanced HIV may be because, these are the ones that are more likely to utilize health services more frequently and hence more likely to keep to follow-up and be constantly reminded of the need to take their medications.

The significantly higher odds of nonadherence in children who failed first-line ART compared to those who did not was as expected; as several studies have shown that non-adherence to ART is one of the major risk factors of ART failure.^[5,13,14]

In our study, forgot to take medications (46.7%) which was the most common reason for non-adherence, was similar to an Ethiopian study^[33] where this reason accounted for 33.9% cases of nonadherence. In another study, this reason again accounted for 65.6% of nonadherence.^[34] The next common reason for nonadherence was: Ran out of medicine (20%).

The children who ran out of medicine did so, not because medicines were not available but because they failed to keep their appointment dates.

Majority (20/30, 66.7%) of the children in our study with nonadherence were 5 years and below. This may be another contributory reason for nonadherence since they were unlikely to remember to take their medications or keep hospital visits as these are the responsibilities of their parents/care givers.

One of the limitations of our study is the problem of recall bias by children or their caregivers during the collection of the information on ART adherence, since we measured adherence using self-reports. This has the potential therefore, of overestimating the rate of adherence and this may explain our low nonadherence rate.

The rate of non-adherence to ART was low in this study with the commonest reason for non-adherence being: Forgot to take medications. The low rate of nonadherence was attributed to the repeated adherence counseling patients and their caregivers get during each clinic follow-up visit and the use of alarm clocks daily for reminding them of when the next ARV dose will be. This practice should be encouraged. It is recommended that the low nonadherence rate should be improved on, by calling parents and caregivers on their Global System for Mobile phones to remind them of their clinic appointment dates to prevent the problem of running out of medications.

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