ORIGINAL RESEARCH ARTICLE
pISSN 0976 3325 | eISSN 2229 6816
Open Access Article
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A Longitudinal Study on Adherence to Anti Retroviral Therapy and Its Determinants in Telangana State

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Financial Support: None declared
Conflict of Interest: None declared

How to cite this article:
Gorantla M, Malhotra VM, Kondagunta N. A Longitudinal Study on Adherence to Anti Retroviral Therapy and Its Determinants in Telangana State. Natl J Community Med 2019;10(2):50-54.

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Date of Submission: 23-10-18
Date of Acceptance: 30-01-19
Date of Publication: 28-02-19

ABSTRACT

Introduction: India is among the list of countries with highest HIV prevalence. Adequate viral suppression requires strict adherence to antiretroviral therapy (ART). This research was conducted to study the clinico-demographic profile of study population and to study the barriers to treatment adherence.

Methodology: This is an observational follow up (longitudinal) study done on 142 patients which included all newly diagnosed, sero positive, adult patients, enrolled at an ART centre and started on treatment during the months of December 2012, January 2013, February 2013, using a pre designed, pre tested questionnaire. They were visited again after a year and adherence was calculated and determinants of adherence were studied.

Results: After one year 129 patients remained, of which 49.61% patients had good adherence and 50.39% patients had poor adherence. Risk factors associated with poor adherence were male sex, urban residence, lower socio economic status, illiteracy, unskilled occupation, spouse negative for HIV, addictions like alcoholism, smoking, experience of drug side effects, early WHO clinical stage, low BMI, opportunistic infections and depression.

Conclusion: There are many risk factors for non adherence many of which are preventable but are not emphasized in the national programme. National programmes must take these into account to strengthen HIV care.

Keywords: ART adherence barriers, longitudinal study

INTRODUCTION

HIV continues to be a major global public health issue. WHO estimated that 36.7 million (34.0-39.8 million) people were living with HIV at the end of 2015 globally. Sub-Saharan Africa remains the most severely affected, with an estimated prevalence of 4.4%.[1] India has the third largest HIV epidemic in the world. In 2015, the estimated prevalence of HIV in India at 0.26% translates to 2.1 million People Living with HIV (PLHIV). During the same year, there were estimated 68,000 deaths due to AIDS-related illnesses.[2]

The Government of India demonstrated its commitment to combat HIV with the launch of National AIDS Control Programme (NACP-1) in 1992.[3] The programme has evolved over a period of time and the present programme (NACP-IV) aims to accelerate the reversal of the HIV epidemic through key strategies of intensifying and consolidating preventive services, promoting comprehensive care, support and treatment, expanding behaviour change communications, building capacities at all levels and strengthening strategic information management system. Provision of uninterrupted quality and free first- and second-line Anti-Retroviral Treatment (ART) to all eligible PLWHA through

ART, Link-ART, ART-plus centres and Centres of Excellence are some of the pillars of NACP-IV.[4]

ART once initiated is a life-long process. Hence adherence to ART is as relevant as its initiation. This aspect has not been adequately researched in India and has never been studied in newly formed state of Telangana which ranks 7th in the prevalence of HIV in India.[5] The present study endeavours to fill this knowledge-gap by studying the prevalence of non adherence and demographic, behavioural, social and programme-related determinants of non-adherence to ART.

MATERIALS AND METHODS

This is an observational follow up (longitudinal) study done on all newly diagnosed (diagnosed on or after 1st January 2012), sero positive, adult patients, enrolled at an ART centre in Telangana state and started on treatment during the months of December 2012, January 2013, February 2013. This included a total of 267 patients. Pregnant women, acutely ill patients and those unwilling to participate in the study were excluded.

A sample size of 142 was calculated based on prevalence of non-adherence as 50% (verbal communication by medical officer in charge of the ART Centre), absolute precision of 10% was taken. With level of significance of 95%, and anticipated loss to follow up and case fatality rate within first year as 20% each.

This study was conducted at an ART centre which is a government-owned facility attached to the district hospital where ART drugs are provided free of charge.

A pilot study was conducted from 1st to 15th of October on 30 patients to assess feasibility of the research project, refine questionnaire and establish content validity. First interview & clinical examination was conducted from 1st December 2012 to 28th February 2013. Follow up interview and clinical examination was conducted from 1st December 2013 to 28th February 2014. (One year following the first interview).

The questionnaire used was semi structured and contained three parts. In first part, socio demographic data was included. The second captured data on relevant anthropological, behavioural, clinical and laboratory variables. Depression was scored separately using Kessler psychological distress scale (K 10) questionnaire.[6] This is a 10 item validated and widely used tool appropriate for outpatient setting. The 5 possible responses range from "none of the time" to "all of the time" and are scored from 1 to 5 and then summed to give a total maximum score of 50. Those who were found to be depressed were referred to department of psychiatry. The 3rd part of the questionnaire was completed 1 year later after the first interview to identify the adherence rates and reasons for non-adherence. The above data was collected after acquiring written informed consent from the patient. Permission to conduct the study was obtained from the Medical Superintendent of the district hospital and the District Coordinator of hospital services (DCHS).

Ethical clearance: Ethical clearance to conduct the study was obtained from the institution's ethical committee.

Adherence: Study subjects who had taken > 90% of the prescribed doses were considered as adherent as a minimum of 90% adherence is recommended for good viral suppression.[7] Currently this is calculated at the ART centre by pharmacy refill tracking method where patients collecting medications regularly on due dates are assumed to be adhering to treatment. Number of days delayed is taken as number of doses missed.

Interview and examination were conducted during the OPD hours of ART centre after their examination by medical officer and dispatch of their drugs. It was conducted in complete privacy with the help of ART counselors. Patient's ART number, residential address and phone number were recorded on their individual proforma to approach them during follow-up.

ART centre was visited again from 1st December 2013 (one year following the commencement of study) to 28th February 2014 when patients came for monthly supply of drugs and clinical examination. Their adherence was calculated for one year based on records at ART centre. Reasons for poor adherence were recorded.

Loss to follow up (LFU) cases were taken to have poor adherence. Among the LFU cases who could be reached at their homes, only clinical examination for opportunistic infections, BMI, reasons for disengaging from care could be recorded. Laboratory tests like CD4 count and haemoglobin could not performed in the field due to logistic difficulty.

Data obtained was analysed and presented using appropriate tests. The data was entered in excel sheet and analysed for proportions. Mean and standard deviations were calculated. Influence of socio demographic factors on adherence was estimated using odds ratio & 95% confidence intervals using the software SPSS version 20.

RESULTS

In the present study majority i.e. 92 subjects were males (64.8%) and 50 were females (35.2%).

Table 1- Distribution of study subjects based on socio demographic profile (n=142)

Variable	Males (n=92)	Females (n=50)	Total (n=142)
Age (years)			
15- 25	4 (2.817)	4 (2.817)	8 (5.63)
26-35	33 (23.24)	23 (16.2)	56 (39.44)
36-45	34 (23.94)	14 (9.86)	48 (33.8)
≥ 46	21 (14.79)	9 (6.34)	30 (21.13)
Marital status			
Married	72 (50.7)	41 (28.87)	113 (79.57)
Unmarried	4 (2.817)	4 (2.817)	8 (5.63)
Widowed/ divorced/separated	16 (11.27)	5 (3.52)	21 (14.8)
Education			
Illiterate	32 (22.53)	8 (5.63)	40 (28.2)
Upto 5th class	27 (19)	13 (9.2)	40 (28.2)
6th to 10th class	29(20.4)	28 (19.7)	57 (40.1)
Intermediate	1 (0.7)	1 (0.7)	2 (1.4)
Graduate	3 (2.1)	0 (0)	3 (2.1)
Occupation			
Unskilled	33 (23.2)	8 (5.6)	41 (28.9)
Semi skilled	6 (4.2)	10 (7)	16 (11.3)
Skilled	50 (35.2)	31 (21.8)	81 (57)
Professional	3 (2.1)	1 (0.7)	4 (2.8)
Socio economic status (Modified B.G Prasad)			
Upper high	2 (1.4)	5 (3.5)	7 (4.9)
High	20 (14.1)	23 (16.2)	43 (30.3)
Upper middle	23 (16.2)	7 (4.9)	30 (21.1)
Lower middle	36 (25.4)	10 (7)	46 (32.4)
Poor	11 (7.7)	5 (3.5)	16 (11.3)
Place of residence			
Rural	67 (47.2)	39 (27.5)	106 (74.6)
Urban	25 (17.6)	11 (7.7)	36 (25.4)
Type of family			
Nuclear	82 (57.7)	43 (30.3)	125 (88)
Joint	8 (5.6)	5 (3.5)	13 (9.2)
3 generation	2 (1.4)	2 (1.4)	4 (2.8)

Figure in parenthesis indicate percentage.

Table 2- Distribution of study subjects based on reasons for poor adherence (n=55)

Reasons for poor adherence	Number (%)
Depression	44 (30.99)
Financial difficulty	39 (27.46)
Busy	31 (21.83)
Pill burden due to opportunistic inf	23 (16.2)
Marital discord	11 (7.75)
Forgot	4 (2.82)
Side effects	3 (2.11)
Abandonment by family	2 (1.41)

Table 3- Socio demographic factors associated with poor adherence

Variable	OR (95% CI)	pValue
Male sex	4.02(1.88-8.59)	0.0003
Urban place of residence	2.3 (1-5.28)	0.0498
Low socio economic status	5.71(2.63- 12.41)	0.0001
Illiterate	2.82(1.24-6.416)	0.0134
Unskilled occupation	5.71(2.63- 12.41)	0.0499
Negative status of spouse for HIV*	104 (24.4-443.2)	0.0001

OR= Odds Ratio

We found that 78.88% belonged to economically productive age group (16-45 years). Smaller proportion of the study subjects (21.13%) were seen in more than 45 years age group. The mean age was 39.33 ± 10.29 SD and the range is 18 to 70 [Table 1).

Most of the study subjects were married. Most of the subjects were educated between classes 6 and 10 and only small minorities were graduates. A majority of the subjects were skilled labourers and professionals were only 2.8%. Majority belonged to lower middle class, resided in rural areas and belonged to nuclear families. [Table 1]

At the end of one year 129 patients remained. Of this a total of 64 patients (49.61%) had good adherence and 65 patients (50.39%) had poor adherence LFU cases were taken to have poor adherence.

Out of 65 cases of poor adherence, 10 cases of LFU could not be reached. Multiple responses were obtained for the above question. We found that depression was the most common cause for poor adherence followed by financial difficulty, being busy, and pill burden due to opportunistic infections [Table 2].

We found that a total of 50 males and 15 females had poor adherence levels. 47.69% males and 20% females reported that disinterest to continue to live with HIV (depression) was the reason for missing doses. 40% males and 20% females reported financial difficulty as the reason for missing doses. 35.38% males and 12.31% females reported that they were busy as the chief reason for missing doses. More than one reason was given in several instances for missing doses.

We found that males were at higher risk of having poor adherence compared to females. Urban place of residence, lower socio economic status, illiteracy and unskilled nature of occupation were at higher risk of having poorer adherence. It was found that sero discordant couples (couples where one spouse is positive and another is negative) were 104 times more at risk of having poor adherence compared to sero concordant couples (couples where both are positive). This category includes only married patients with live spouses [Table 3].

Patients who were alcoholics, smokers and those who experience drug side effects were at greater risk of poor adherence. We found that patients in stage 4 disease are more likely to be adherent to ART than patients in other clinical stages. Underweight BMI, presence of opportunistic infections and severe depression are associated with poorer levels of adherence [Table 4].

Table 4- Patient related factors associated with poor adherence

Variable	OR (95% CI)	pvalue
Alchoholic	640.7(103.4-3967.9)	0.0001
Smoker	89.6(23.9-334.5)	0.0001
Drug side effects	14(1.73-113.29)	0.0134
4 th stage HIV	0.46(0.36-0.6)	0.012
Underweight BMI	2.5(1.230-5.092)	0.0114
Opportunistic infection	136.9(29.3-639.4)	0.0001
Severe depression	40(5.77-277.05)	0.0004

OR= Odds Ratio

DISCUSSION

At the end of one year 129 patients remained. Of this a total of 64 patients (49.61%) had good adherence and 65 patients (50.39%) had poor adherence.LFU cases were taken to have poor adherence. A cross sectional study done by Cauldbeck et al [8] found the rate of adherence to be 60%, Study by Golin CE et al [9] found a 71% rate of adherence after 4 weeks study period and a cross sectional study done by Gordillo V et al,[10] in their study found a 57.7% rate of adherence.

It was found that older patients had better adherence but this was not statistically significant a ($p > 0.05$). Similarly study done by Cauldbeck et al [8] also found older patients to be more adherent to therapy but this was not statistically significant ($p = 0.325$). Studies by Golin CE et al [9] and Gordillo V et al [10] found association of older age with better adherence.

We found that males were at a greater risk of having poor adherence compared to females. Our study findings were consistent within the results of study done by Yuri Sasaki et al[11]. 68.1% of females had good adherence compared to 31.9% males. This might be because female patients may have had greater motivation to adhere to ART due to the responsibility caring for children and their family.

Our study found that patients residing in rural areas had good adherence compared to those living in urban areas. This association was statistically significant (OR=2.3). These findings were consistent with the finding of Mary B Cauldbeck et al [8] where rural population (66.7%) showed good adherence levels. This may be due to presence of lesser stressors in rural area compared to urban area which facilitate adherence. A statistically significant association was found between illiteracy and poor adherence. These findings were consistent with the findings of studies done by Sarna et al, [12] who found that illiterate patients were 4.28 times at a grater risk of having poor adherence.

We found that patients from low socio economic status had a higher risk of having poor adherence than patients from higher socio economic status. These findings were consistent with the findings of studies done by Mary B Cauldbeck et al[8] where 45.5% of patients living in absolute poverty had poorer adherence. Financial constraints act as a barrier to adherence. Affordance of transportation to care centres, job security etc associated with higher economic status patients act as facilitators to remain in care. Couples where both were sero positive were more adherent to treatment. This can be due to higher emotional support, visiting the centre together, fear of dependent members getting orphaned act as facilitators for good adherence. The findings of this study were consistent with that of Amderbir A et al.[13] Our study showed a significant association between alcoholism, smoking and poor adherence. These findings were consistent with the results of study done by Seth C Kalichman et al [14] which found that 53% of alcoholic patients had poor adherence. This is because addictions are known to be responsible for poor self care and diversion financial resources away from vital concerns such as health.

Drug side effects adversely impacted adherence. A study conducted by A Sarna et al[12] found that 43.8% patients who experienced drug side effects had poor adherence compared to only 12.6% patients who had no adverse drug side effects (OR-5.4). Study done by Cauldbeck et al [8] also reported that patients experiencing side effects were less likely to be adherent to ART.

Our study found that patients in stage 4 disease are more likely to be adherent probably because of a feeling of well-being in those in earlier stages could be a barrier to treatment. This also seen in studies done by Mary B Cauldbeck et al.[8] We found that opportunistic infections adversely affect adherence probably due to pill burden. Study done by Sarna et al[12] found that as the number of medication increases, adherence decreases. Similar findings were found in a study done by Mary B Cauldbeck et al.[8] We found that low BMI adversely affects adherence. Study done by Mary B Cauldbeck et al[8] found similar results. Hence nutritional intervention must be incorporated into the programme.

We found that as depression increases risk of poor adherence also increase. Similar results were also reported from studies done by Sarna et al[12] and Amberbir A et al.[13] This area is amenable for intervention.

CONCLUSION

Socio demographic factors such as male sex, place of residence, socio economic status, literacy etc played an important role as determinants of adherence in this study as were habits and addictions like alcoholism and smoking. Most common cause

of poor adhere was depression followed by financial difficulty.

RECOMMENDATIONS

Inspite of India's best efforts at reversing the HIV epidemic, drop out rate from ART as well as poor adherence rates are high. The present study has brought out some barriers to adherence at a local level. The findings are compelling enough to initiate further studies at regional and national levels and to take corrective measures.

Ethical approval: The study was approved by the Institutional Ethics Committee.

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