

Full Length Research Paper

Impact of pharmacist provided education on medication adherence behaviour in HIV/AIDS patients treated at a non-government secondary care hospital in India

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A single group pre-post test study evaluated the impact of a pharmacist provided education session on medication adherence behaviour in 104 HIV/AIDS patients receiving highly active Anti Retroviral Therapy. A brief medication questionnaire was administered to eligible patients at baseline and follow up to assess their reported medication adherence and barriers to adherence. The number of subjects reporting greater than 95% adherence increased significantly between baseline (n = 39 (43%)) and final follow up (n = 79 (80%)). Pharmacist provided education sessions were found effective in improving medication adherence behavior in HIV/AIDS patients.

Key words: Medication adherence, brief medication questionnaire (BMQ), patient education, pharmacist, HIV/AIDS.

INTRODUCTION

Introduction of Highly Active Antiretroviral Therapy (HAART) has transformed the Human Immunodeficiency Virus (HIV) infection from a fatal to a manageable disease by decreasing the viremia and increasing the CD4 cell count, and preventing opportunistic infections and deaths (Miller and Hays, 2000). Studies have revealed that more than 95% of adherence to HAART is essential to achieving the desired therapeutic outcomes, decrease viremia load and prevent the development of drug resistant HIV strains (Stone, 2001; Sethi et al., 2003). Research studies have shown that a decrease in 10% adherence increases the mortality rate by 16% (Mills et al., 2006). In diverse cultural and geographical settings, the average rate of adherence with antiretroviral therapy is reported as 50 to 70% due to reasons such as poor socio-economic status, disclosure of serostatus, health beliefs, lack of social support and regimen complexity (Weiser et al., 2003).

In India, about 2.5 million people are suffering from AIDS and need HAART (Damodar et al., 2010). The

Indian Government offers free antiretroviral worth INR 13,340 (US \$ 266 million) through National AIDS Control Organisation (NACO) identified antiretroviral therapy (ART) centers. It is expected that by 2012, about 300000 adults and 40,000 children will be benefiting across the country receiving free ART supply (Retty et al., 2010).

Despite of consistent efforts to improve the access to ART, adherence to antiretroviral remains a challenge. Studies conducted in Western and South India have shown that lack of social support, poor understanding about the disease and its progression and poor accessibility to ART centers are the reasons for non-adherence (Shah et al., 2007; Kumarasamy et al., 2005). Goujard et al. (2003) have shown the positive influence of patient education regarding the disease and its management on medication adherence which was reflected in the improved health status of study patients in the intervention group. A Cochrane meta analysis of studies on the effect of educational interventions on medication adherence showed a non-significant positive influence of educational intervention on medication adherence behaviour in HIV patients on HAART (Rueda et al., 2006).

The present study was conducted to assess the impact of pharmacist provided education on medication

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adherence behaviour in AIDS patients at a non-government AIDS care and research hospital.

MATERIALS AND METHODS

This single group pre-post test interventional study was conducted over a period ten months at Asha Kirana Hospital, a non government AIDS care and research center in Mysore, South India. About 1200 HIV infected patients from rural and semi urban areas had registered at this center. Registered HIV positive patients received essential investigations, and care at free of cost at the study site. Patients received free medicines from local ART center which is 5 km away from the study site.

Male and female HIV infected patients aged more than 18 years who were on antiretroviral therapy for at least one month were eligible for enrolment into the study. Enrolment commenced in August, 2007 and was completed in May, 2008. Written informed consent was collected from all the enrolled patients. For illiterate patients, informed consent was taken in the presence of impartial witness after explaining the objectives of the study in vernacular language. Institutional Research and Ethics Committee of JSS College of Pharmacy and Asha Kirana Hospital approved the study.

The Brief Medication Questionnaire (BMQ) (Svarstad et al., 1999), a sensitive tool to assess medication adherence behaviour was administered to the study patients at baseline and at the final follow-up visit. The BMQ consists of four screens; regimen screen, belief screen, recall screen and access screen. The regimen screen consists of five items and asks patients about the medications they are currently taking. Patients were asked to list the name of each medication, frequency of medication per day, number of days and times they have received each medication along with the number of times medications had been missed in recent weeks. The belief screen of BMQ contains two questions to assess whether patients had any difficulty with any of the medications, and whether the medication bothered them in any way. The two-item recall screen measures potential problems the patient may have in remembering to take all doses of their medications. The, 2- item access screen evaluates the patient's difficulty in buying and refilling their medications in time. A score of >1 in any screen is considered as a positive screen, which suggests that the patient has some non-adherence with their medication regimen, or a barrier to adherence. A score of zero (a negative screen) indicates that the patient did not report any non-adherence or barrier to adherence. The higher the BMQ screen score, the higher the rate of possible medication non-adherence.

The patients' demographic details, and past medical and medication history were collected using a data collection form. A structured education module was prepared in consultation with the AIDS counselors of Asha Kirana hospital prepared for this study. The module contained information about the disease, recommended diet, medications and importance of adherence to ART. Patient information leaflet (PIL) was prepared in consultation with the doctors treating at the hospital and included disease related information such as the pathogen responsible, modes of transmission, signs and symptoms, medication related information, recommended diet and necessary lifestyle modifications. Content and language validation was done. Flesch Readability Ease (FRE) score and Baker Able Leaflet Design (BALD) criterion was applied to assess the leaflet's readability and design (Adepu and Nagavi, 2003).

All enrolled patients received the structured education during each visit in a private setting and were given PIL. For illiterate patients, education was provided in the presence of a literate family member or friend as agreed by the patient. The same family member/friend accompanied the study patient during further visits. At baseline the BMQ questionnaire was administered after collecting the patient's socio-demographic, and disease information.

The questionnaire was re-administered at final follow up to assess the impact of patient education on adherence behaviour. The collected data was analysed using SPSS (Statistical Package for Social Sciences), version 11. The Chi-square test and Pearson correlation analysis were used to analyse the influence of variables on BMQ scores. Statistical significance was set at $p < 0.05$. Percentage of self-reported adherence was calculated using the following formula:

$$\% \text{ adherence} = \frac{\text{Total number of doses to be consumed} - \text{missed doses}}{\text{Total number of doses to be consumed}} \times 100$$

The patient was considered as adherent if he or she reported taking $\geq 95\%$ of the prescribed doses. BMQ data were expressed as mean \pm standard deviation.

RESULTS

Out of 104 enrolled patients, 90 patients (86%) completed the study. Fourteen patients were lost to follow up at various stages of the study. The study population consisted of 58 male and 32 female patients with a mean age of 32 years. The majority of study patients (32%) were illiterate, 51% were from rural areas and 31% were unemployed. The average annual income of 42% of the study population was less than Indian Rupees 50,000 (USD 1069) per annum. The majority patients were prescribed with 3 ART drugs and other drugs for co-morbidities. The socio-demographic details of the study patients are summarized in Table 1.

The percentage medication adherence to antiretroviral agents was calculated from baseline (the time of enrollment) to final follow up using the % medication adherence formula. At baseline 43% of patients reported $\geq 95\%$ of adherence and at the final follow up, this increased to 88%. The time course of changes in medication adherence from baseline to final follow up are presented in Figure 1.

The mean BMQ score of the study patients at baseline was more than 1 in all screens, indicating patients reported non-adherence or a barrier to adherence. However at final follow up, a significant decrease ($p < 0.01$) in BMQ scores was observed in regimen, belief and access screens. Results of BMQ scores in various screens are summarized in Table 2.

A significant improvement ($p < 0.01$) was observed in the number of patients recording a negative screen. The results summarising the shift of patients from a positive to a negative screen are presented in Table 3.

A negative association was observed between educational level, income and disease duration on various BMQ screen scores. Pearson correlation (two tailed) of continuous variables with BMQ scores are presented in Table 4.

DISCUSSION

Medication adherence is an essential determinant in the

Table 1. Socio demographic details of HIV patients.

Variable	Number of patients
Sex	
Male	58 (64.5%)
Female	32 (35.5%)
Age (in years)	
21- 30	21 (23.3%)
31-40	40 (44.5%)
41-50	10 (11.1%)
51-60	19(21.1%)
Educational Status	
Illiterate	32 (35.5%)
Primary school education	16 (17.7%)
Secondary school education	21 (23.3%)
Pre University course (10 + 2)	11 (12.2%)
University graduate	10 (11.1%)
Annual Income (in Indian Rupees)	
< 50,000 (< US \$1200)	38 (42.2%)
50,000 – 1,00,000 (US 1200 - \$ 2400)	31 (34.4%)
>1,00,000(>US \$2400)	21 (23.3%)
Employment status	
Employed	62 (68.8%)
Unemployed	28 (11.2%)
Residence	
Rural	46 (51.1%)
Urban	44 (48.8%)
Antiretroviral drugs	
Zidovudine + Lamivudine + Nevirapine	2 (2.2%)
Lamivudie + Stavudine + Nevirapine	62 (68.8%)
Lamivudine + zidovudine + Efavirenz	26 (28.8%)
Number of medications	
3	41(45.5%)
4	13 (14.4%)
5	10 (11.1%)
7	4 (4.4%)
8	22 (24.4%)

therapeutic success of any therapy (Weiss et al., 2003). Although, no gold standard method is available to assess adherence behaviour, self-reporting methods such as surveys, interviews and diaries, clinical assessments, pill counts, directly observed therapy, prescription refill method, biological assays, and medication event monitoring systems are commonly used to assess adherence behavior (SyBecker, 1995). In the present

study, the brief medication questionnaire, a self reporting method was adopted to study the adherence behaviour in enrolled patients (Svarstad et al., 1999). Among 104 enrolled patients, 14 patients were lost to follow-up, for reasons like fear of serostatus disclosure, absence of symptoms, financial and transportation problems. A systematic review of the literature regarding the factors responsible for poor adherence to medication in

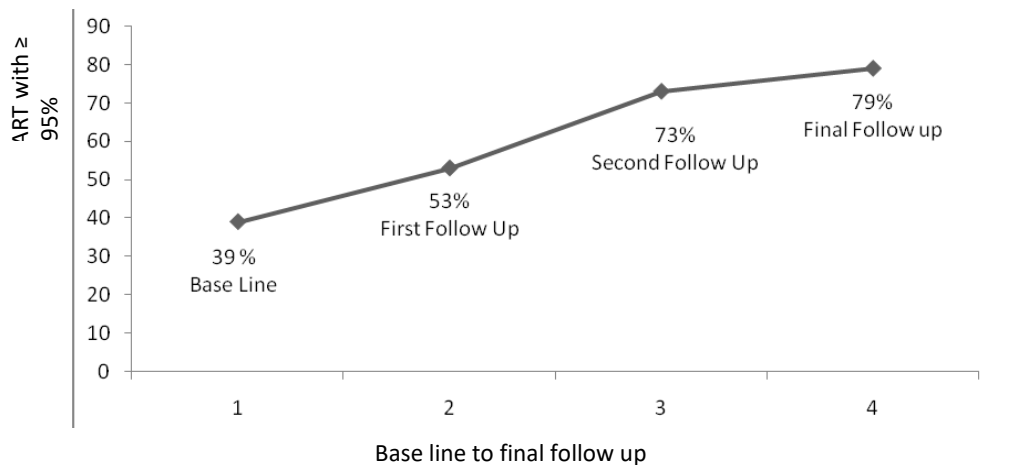


Figure 1. Percentage of subjects reporting $\geq 95\%$ adherence to ART from baseline to final follow up: 1) Base line; 2) first follow up; 3) second follow up; 4) final follow up.

Table 2. Comparisons of base line and final follow-up BMQ score.

Comparison of post education BMQ with pre education BMQ scores N = 90 patients			
BMQ screen	Baseline mean + SD scores	Final follow-up mean + SD scores	P value
Regimen screen	2.34 +1.36	0.54 + 0.72	P < 0.01
Belief screen	1.35+ 0.73	0.44+0.56	P < 0.01
Recall screen	1.51+ 0.64	0.55+0.62	P = 0.853
Access screen	1.07+ 0.86	0.33 +0.49	P < 0.01

P < 0.05 is considered as statistically significant.

Table 3. Influence of education sessions on shift of patients from positive screen to negative screen.

BMQ screen	Follow-up (N=90)	No. of patients in negative screen	Chi-square	P Value
Regimen screen	Base line	2	46.2	P<0.01
	Final follow-up	52		
Belief screen	Base line	14	22.7	P<0.01
	Final follow-up	53		
Recall screen	Base line	7	31.5	P<0.01
	Final follow-up	49		
Access screen	Base line	30	10.5	P<0.01
	Final follow-up	61		

P < 0.05 is considered as statistically significant.

developing countries was observed as cost of the medication, social stigma, alcohol abuse, and structural barriers like lack of transportation (SyBecker, 1995; Carrieri et al., 2001). Similar reasons were also observed in the present study.

Many studies have demonstrated a positive influence of educational intervention on medication adherence behaviour in patients taking HAART. Rogers AS et al observed that educational intervention increased medication adherence more than 95% in two thirds of the

Table 4. Pearson correlation of continuous variables with BMQ.

Continuous variables	Pearson correlation sig (2-tailed) N	Regimen screen	Belief screen	Recall screen	Access screen
Age	Pearson correlation sig (2-tailed) N	-0.16, 0.879, 90	0.015, 0.892, 90	0.054, 0.613, 90	-103, 0.332, 90
Education	Pearson correlation sig (2-tailed) N	** -0.557, 0.000, 90	* -0.261, 0.013, 90	** -0.548, 0.000, 90	0.197, 0.063, 90
Income	Pearson correlation sig (2-tailed) N	-0.209, 0.048, 90	-0.095, 0.372, 90	-0.162, 0.127, 90	0.038, 0.721, 90
Comorbidity	Pearson correlation sig (2-tailed) N	0.143, 0.179, 90	0.049, 0.646, 90	0.137, 0.198, 90	-0.036, 0.735, 90
Disease duration	Pearson correlation sig (2-tailed) N	** -0.162, 0.127, 90	0.127, 0.232, 90	** -0.066, 0.535, 90	0.071, 0.509, 90

**Correlation is significant at the 0.01 level (2-tailed); *correlation is significant at the 0.05 level (2-tailed).

study population at the final follow up (Rogers et al., 2001). Lyon et al. (2003) studied a 12 week group educational intervention that resulted in an increase in CD4+ cells/ μ L of more than 500 in 56.5% of subjects whose baseline CD4+ cells/ μ L was less than 200, and also increased the self-reported medication adherence (> 95%) in 91% of the study population.

Goujard et al. (2003) in a prospective randomized controlled study showed an impact of patient education on adherence and knowledge in the experimental group at 6 months, which was maintained at 12 and 18 months. A delayed increase in adherence was observed in the control group at 12 months. The patients' health status improved in 56% of the experimental group subjects and 50% of the control subjects (Kumarasamy et al., 2005). In the present study, the mean BMQ scores at baseline in three screens of the questionnaire were found to be positive. The majority of study patients reported no difficulty in refilling their antiretroviral medications from the government ART center. Though the patients had access to free ART, the access screen score was positive reflecting the difficulty in receiving free ART medications. The patients had to travel (around 5 km) to the Government ART centre to collect their medicines, which was located at different premises. For some patients this distance and

travel was a 'barrier' resulting in positive score in access screen. The patient education probably improved the patients' understanding of importance of adherence to ART and resulted in improved behavior.

The highest baseline scores were for the regimen screen due to lack of knowledge amongst HIV/AIDS patients regarding details of their medications. Several studies have also concluded that lack of knowledge about medications such as the name, dose, frequency and indications is an important reason for non-adherence (SyBecker, 1995; Carrieri et al., 2001). In the present study, a significant number of patients shifted from positive screen self-reported non-adherence) at baseline to negative screen (self-reported adherence) in the final follow-up. However as the study design did not have a control group we cannot be certain that pharmacist provided education alone accounted for improved adherence behaviour. When compared to the baseline mean BMQ screen scores, a significant ($p < 0.01$) reduction in the regimen, belief, and access BMQ screen scores was observed in the final follow-up. This reduction in the BMQ screen scores indicates an improvement in the self-reported adherence status of the study patients after receiving pharmacist provided education sessions. At final follow up, the number of patients reporting difficulty in remembering to take their

medications was decreased and the number of patients moving to negative screen of BMQ was increased, showing an increased self-reported adherence. The aforementioned findings suggested that education about the disease and the prescribed medications will improve understanding about the importance of adherence to HAART. Several studies have also corroborated the role of pharmacists in improving the HIV patient's medication knowledge, adherence and improved therapeutic outcomes (Chesney et al., 1999; Wagner et al., 2001).

In the present study, no association was found between income, academic education and duration of antiretroviral therapy and BMQ regimen screen scores. It was also observed that educational and duration of treatment with ART was negatively associated with BMQ recall screen scores. This was observed more in the illiterate patients. Structured education of patients can help to be overcome this problem. Patients who were on ART for a shorter duration of time had more difficulty in recalling their medications. Several studies have identified the reasons for decreased adherence as low income, poor educational status and shorter duration of treatment with antiretroviral agents (Talam et al., 2008; Nwokike, 2005).

The present study findings suggest that poor knowledge about their disease and its treatment

was the main reason for low levels of adherence. Improvement in the scores of various screens at final follow-up suggested that education had a positive influence on adherence behaviour. Tuldra et al. (2000) have shown that psychoeducative intervention has a role in enhancing adherence behaviour in HIV patients (Nwokike, 2005). The Cochrane review of the literature on patient support and education to promote adherence to HAART has shown patient support and educational interventions improve medication adherence behaviour, which was demonstrated by decreased viral load and increased CD4 cell count (Rueda et al., 2006). A similar impact was observed in the present study showing positive influence of education on adherence to HAART in HIV patients.

Conclusion

Our results suggest that a single, structured education session provided by a pharmacist may improve the understanding about HIV and HAART amongst south Indian patients, and have a positive effect on medication adherence behaviour.

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