Assessment of Quality of Life in a Cohort of Newly Diagnosed Patients on HAART Regimen, in Resource Restricted Tribal Region of Chhattisgarh, India: A Prospective Study

Harminder Singh, Kamalpreet Kaur, Navin Dulhani[1], Akash Bansal[2], Bithika N. Kumar[3], Vinod Kumar Singh Chouhan[4]

Department of Pharmacology, GGS Medical College, Faridkot, Punjab, [1]Departments of Medicine, [2]Biochemestry, [3]Pharmacology, [4]SPM, Government Medical College, Jagdalpur, Chhattisgarh, India

ABSTRACT

Background: Highly active antiretroviral therapy regimens have resulted in the systemic/clinical healing for human immune deficiency virus-infected patients but the consequence of antiretroviral therapy on the whole quality of life has become a major concern. The current study correlates the relationship of quality of life with successful highly active antiretroviral therapy. **Aim**: To determine the health-related quality of life in human immune deficiency virus-infected patients on highly active anti-retroviral therapy regimen in tribal region of Chhattisgarh. **Design:** An open label prospective study. **Materials and Methods:** Health-related quality of life was assessed using a standardized questionnaire, the Medical Outcomes Survey Short Form 36. Physical health summary scores and mental health summary scores were compared of pre-Highly Active Anti-Retroviral Therapy (at baseline) and post 12 months of therapy. **Results:** The increase in CD4 cell counts was extremely significant ($P < 0.0001$). The Physical Composite Summary (P value = 0.0003) improved significantly, whereas the Mental Composite Summary (with a baseline value of 40.7), post 12 months, was calculated as 42.8 (P value = 0.2371) and was statistically not significant. **Conclusion:** Efficacy measurement is the key ingredient of highly active anti-retroviral therapy, which must also include assessment of health-related quality of life to maximize the holistic approach towards disease.

Key words: Highly active antiretroviral therapy, Health-related quality of life, Medical outcomes survey short form 36 questionnaire, Tribal HIV patients

INTRODUCTION

It is estimated that in 2007, about 2.31 million Indians were living with Human Immune Deficiency Virus (HIV) (1.8-2.9 million) with an adult prevalence of 0.34%[1] According to recent report, high prevalence of HIV has been reported from western region (Mumbai–Karnataka), Nagpur, north eastern state of Manipur–Nagaland and some part of southern state (Tamil Nadu–Andhra Pradesh) and around 60% of people living with HIV/AIDS live in these six high-prevalence states.[1,2] Seven countries including India, China, Thailand, Indonesia, Viet Nam, Myanmar, and Malaysia are reported to have an estimated 100 000 or more people living with HIV: (ranked by the number of people living with HIV in each) that is about 90% of HIV (people living with HIV) load of Asia.[3] In south eastern Asia, India alone accounts for 49% of the people living with HIV in the entire region.[3]

Clinical efficacy of highly active antiretroviral therapy (HAART) has often been measured by reduction in morbidity, mortality, opportunistic infection, declining CD4 count-viral load and severe AIDS-related symptoms,[4] apart from these parameters upgrading of health-related quality of life (HRQoL) of HIV patient is an unobserved or modestly noticed domain.

The annual incidence of newly infected persons with HIV continues to decline and it is universally observed across the countries although this varies strongly between regions. In 1996, the South-East Asia HIV epidemic peaked with 470,000 [410,000-530,000] people estimated to have

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Address for correspondence:
Dr. Harminder Singh, E-mail: dr_harminderchahal@rediffmail.com

acquired HIV infection and 2010 report observed decline by 40% to 270,000 [230,000-340,000 have acquired HIV infection]. These trends reflect a permutation of issues like the expected course of HIV epidemics, greater awareness, behavioral changes including sexual practice, route of transmission and with intensified deterrence hard work, and escalating coverage of antiretroviral therapy (ART).[3,5]

The stepped up coverage of ART led to surge in QoL research rather than finding only efficacy and clinical improvement. According to the World Health Organization (WHO), QoL is defined as "individuals' observation of their position in life in the background of the customs and value systems in which they live and in relation to their ambition, standards, expectations, and concerns."[6] A number of factors related to enhancement in QoL have been documented, like sociodemographic distinctiveness such as male sex,[7] younger age,[8] higher socioeconomic position,[9] and employment,[10] lower HIV viral load,[11] greater CD4+ cell count,[8,11,12] fewer or less inconvenient HIV symptoms,[10] and higher levels of hemoglobin.[13] Low vigor and fatigue has been allied with both physical and psychological morbidity and poor QoL in persons with HIV/AIDS.[14,15]

The National AIDS Control Organization (NACO) in India established inexpensive and generic ART drugs supply chain.[16] With the availability of generic HAART at low cost, an increasing number of HIV-infected individuals are now getting therapy thus ensuring that HIV is no longer a fatal disease, in fact it is now classified as chronic but potentially controllable disease. Many studies in our country have demonstrated the efficacy, safety, and tolerability of HAART.[17,18]

In India, some data has been reported regarding QoL in AIDS patients; however, very few studies have been done on the often neglected resource restricted tribal population.[19,20] This study used a prospective longitudinal, open labeled design incorporating measurements of clinical and psychological parameters to investigate the brunt of HAART on HRQoL in tribal HIV patients of Chhattisgarh.

MATERIALS AND METHODS

Study subjects

Our open label prospective longitudinal observational design study examined the HRQoL status of 75 HIV-positive tribal patients' pre-HAART and at an interval of 12 months during their first year of receiving HAART at the NACO-approved ART center at Government Medical College, Jagdalpur, Chhattisgarh, between January 2010 and December 2011, after approval from institutional ethics committee. All recently diagnosed HIV patients were interviewed only after getting written informed consent. All included tribal patients were initiated on various HAART regimens strictly following the NACO guidelines.[16]

Inclusion and exclusion criteria

The inclusion criteria were newly diagnosed patients, who are free from severe psychiatric or cognitive problems such as mental retardation. Patients suffering from tuberculosis simultaneously, or with life expectancy of less than 4 weeks or not willing to answer the questions were excluded from the study.

Data collection

Baseline information included demographic data (gender, age, route of transmission, educational status and family income). Clinical information included CD4+ cell count, hemoglobin levels, mean weight, mean number of hospital admissions (in last 6 months) and mean number of OPD visits (in last 6 months). HRQoL measurement data with an inclusive Physical Composite Summary (PCS) and Mental Composite Summary (MCS) that was based on Medical outcome Study Short Form 36 (MOS SF-36) scale were collected at baseline and a follow-up visits up till 12 months of treatment.

HRQOL measurement

Patients were asked to respond to questionnaire at enrollment (M0), and at the end of 12 months (M12), which was according to different domain of MOS SF-36 scale. MOS SF-36 is a multi-purpose, short-form health survey with only 36 questions. It gives an 8-scale outline of functional health and well-being gain as well as psychometrically allied physical and mental health summary measures.

MOS SF-36 scale is intended to evaluate eight health concepts: (1) physical functioning (limitations in physical activities because of one or more health problems), (2) social functioning (limitations in social activities because of physical or emotional problems), (3) Physical-related role limitations (limitations in usual role activities because of physical health problems), (4) bodily pain, (5) general mental health (psychological distress and well-being), (6) emotional-related role limitations (limitations in usual role activities because of emotional health problems),

(7) vitality (energy and fatigue), and (8) general health perception.[21] The MOS-SF36 questionnaire has been widely used in studies of QoL in HIV-positive patients in both developed and developing countries, and has performed well in all of these settings.[22,23] This questionnaire was completed at baseline (M0) and after 12 months (M12) of treatment and SF-36 scores were calculated for each subscale.

Statistical analysis

Baseline distinctiveness (demographic, clinical and HRQoL) were summarized by descriptive statistics. Mean, percentages, and standard deviation were calculated wherever appropriate. HRQoL (subclass eight domains) and clinical characteristics/categories pre-HAART Baseline were compared with post HAART 12 months follow up by two sample *t* test. All *P*-values ≤0.05 were considered significant.

RESULTS

Initially 75 patients were enrolled in the study. HRQoL data were intended to be collected of all 75 patients at the scheduled visit at the end of follow up 12 months. However, eight patients lost to follow up, three died during the study. Our study analyzed only 64 patients, whose HRQoL data was available at the end of first year on HAART and completion rate of the study was 85.33%. The overall survival rate was 86%. The remaining 64 patients who completed the follow up in 1 year were evaluated for the following characteristic.

Sociodemographic data characteristics

The male population was 62.7% and the mean age of the study population was 42.6 (±13.5) years [Table 1]. The route of acquisition of HIV infection was heterosexual contact in the majority (96. 88%). Two patients had acquired the infection through blood transfusion. None of the study patient was linked to homosexual and intravenous transmission. Less education was linked to high prevalence of HIV as 50% of the tribal patients were below 5th standard of education. Only 36% of enrolled subjects had a family income of more than 40 US dollars/2,000 rupees.

Clinical markers

Clinical markers improved significantly in the first year of HAART [Table 2]. The increase in CD4 cell counts was extremely significant ($P < 0.0001$) with CD4 cell count mean raised to 270 (±124) as compared to 185 (±113) at baseline. No significant increment was noted in the case of hemoglobin and weight gain post 1 year of HAART therapy. In addition, mean numbers of hospital admissions in last 6 months were significantly reduced to a mean of 2.8 (±1.5) at the follow up compared to 3.63 (±2.1). Similar results were evident for mean number of OPD visits which again show a decline to 7.2 (±2.7) from a value of 8.4 in the last 6 months.

Table 1: Sociodemographic characteristics (*n*=64)

	Demographic data	No.	%
Gender	Male	40	62.5
	Female	24	37.5
Mean age (mean ±SD)		42.6±13.5	
Transmission route	Heterosexual	62	96.88
	Blood	02	3.13
Educational status	Illiterate	17	26.56
	Below 5th std.	32	50
	High school level	11	17.19
	Above high school	04	6.25
Family income (monthly)	Less than 2000 Rupees	41	64
	>2000 Rupees	23	36

Table 2: Clinical follow up data (*n*=64)

	Baseline mean±SD	12 months mean±SD	SE	*P* value
CD4 cell count	185 (±113)	270 (±124)	20.971	0.0001[a]
Hb%	8.56	9.15	5.608	0.91[c]
Mean weight (kg)	46.8 (12.7)	51.3 (11.5)	17.133	0.7932[c]
Mean no. of hospital admission (in last 6 months)	3.63 (±2.1)	2.8 (±1.5)	0.323	0.112[b]
Mean no. of OPD visits (in last six months)	8.4 (±3.8)	7.2 (±2.7)	0.583	0.0415[b]

[a]Highly significant, [b]significant, [c]not significant

Quality of life measurement

During the first year of HAART, seven of the eight MOS SF-36 QoL scales were enhanced significantly, as shown in Table 3. In the case of cumulative scores, only the PCS improved significantly [Table 3]. As per MOS SF-36 scale, subclass social functioning scale was the only showing no significant improvement between M0 and M12 [Table 3], whereas physical functioning, role physical, bodily pain, general health achieved significantly higher gains. As compared to PCS (*P* value = 0.0003) which improved significantly, MCS (with a baseline value of 40.7, post 12 months was calculated to 42.8 *P* value = 0.2371) was not statistically significant. Figures 1a and b summarized the comparative subscale of MOS SF-36 and relationship of PCS and MCS gain.

Table 3: Baseline and follow up HRQoL scores in 12 months (*n*=64)

QOL category	Mean baseline QOL score	Mean 12 month follow up QOL score	Standard error	*P* value
Physical functioning	59	70	3.925	0.0059[a]
Role physical	31	42	3.575	0.0026[a]
Bodily pain	53	69	4.809	0.0012[a]
General health	34	55	3.905	0.0001[a]
Vitality	54	62	2.929	0.0072[a]
Social functioning	42	49	3.340	0.0502[c]
Role emotion	52	61	4.257	0.0365[b]
Mental health	58	63	2.401	0.0393[b]
PCS	38.7	45.2	1.768	0.0003[a]
MCS	40.7	42.8	1.768	0.2371[c]

PCS = Physical composite summary, MCS = Mental composite summary
[a]Highly significant; [b]significant; [c]not significant

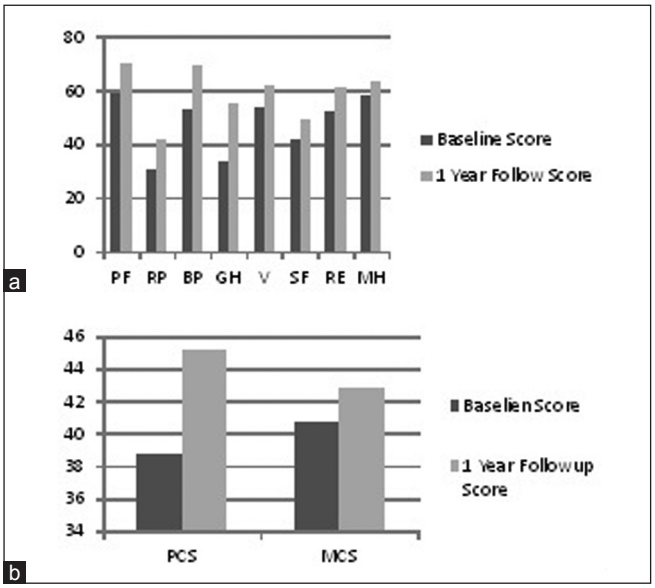

Figure 1: (a) Comparison of eight health domains of MOS SF-36 at baseline and 1 year follow up. PF = physical functioning, RP = role physical, BP = bodily pain, GH = general health V = vitality, SF = social functioning, RE = role emotional, MH = mental health. (b) Comparison of Physical Composite summary (PCS) and Mental Composite Summary (MCS) at baseline and 1 year follow up

DISCUSSION

A three-drug regimen cocktail antiretroviral therapy for HIV disease has been proved to be clinically valuable,[24] this increase in life expectancy suggest clinically significant enhancement in survival and hence the upholding and improvement of life quality are imperative goals in the treatment of HIV disease. The current study shows that post 12 months of HAART leads to a significant improvement in most dimensions of HRQoL. Our results confirm previous results that HAART initiation is accompanied by a general improvement of HRQoL among treated HIV-infected patients.[25]

All physical dimensions of HRQoL improved, as indicated by the significant increase in the PCS score; however, the achievement of treatment was less striking on the MCS gain. The Social functioning scale was the only MOS SF-36 scale subclass showing no significant improvement between M0 and M12. This is unlike the previous reports which show a significant increase in the MCS score rather than PCS score.[22] As divergent to the current study, Liu *et al*. reported that the PCS score following HAART has remained lower than that prior to infection but HAART has enhanced mental health functioning.[23]

Here in this domain, few aspects of our analysis deserve further elaboration. The PCS improvement was noteworthy. An explanation of this could be patients' awareness of effective therapeutic options. Our finding reinforce the fact that patients observation of their QoL is correlated to their capability to function in society and their ability to do well in daily living proceedings.[26]

In our study, MCS score rise was not statistically appreciable as compared to Physical component. This may reflect poor mental preparation of the patients regarding the disease process; high social stigmata attached with the HIV disease and the patient's general perception that HAART being only a mean of life prolongation rather than a definitive cure. The study result may perhaps indicate need for an aggressive approach towards person to person counseling that may be able to improve awareness about the pathophysiology, disease progression, and increased life expectancy with improved quality, more social acceptability and better rehabilitation in the area of focus in this region.

In our HIV-infected cohort, demographic and social factors were found to be vital predictors of HRQoL. Our results included low education and unemployment (leading to low monthly income) associated with high prevalence of the disease. This is consistent with the literature available that education, a surrogate of socioeconomic status, has also been recognized to manipulate QoL. Our scrutiny demonstrated that patients with higher education account better QoL, possibly due to improved understanding about their treatment of ailment, access to health services, or functional status.[27]

Our conclusion discovered restoration of immune function, as evident by the amplified CD4 count and a significant

decline in the mean number of hospital admissions and OPD visits results in a noticeable improvement of HIV/ allied disease processes and reduction of AIDS-related mortality, which reflects the current literature.[28]

The strengths of the current study comprises that the data was extracted from resource-restricted remote tribal population (which has hardly been reported previously) as well as longitudinal follow up. However, the limitations include the small sample size and the psychometric instrument that we used, the MOS SF-36, is a generic HRQoL measurement tool that may not be entirely sufficient to arrest the QoL in totality due to population specific limitations.[29] In our scrutiny, we examined the outcome of HAART as a whole, rather than assessing of precise HAART regimens blend on QoL, at the same time adherence to HAART was not accounted in our analysis.

We valued the NACO inventiveness for introduction of an ART center in a resource constraint setting. However, involvement of more government and non-government regulatory organizations are desirable to force holistic advancement including social rehabilitation and proper psychoanalysis which would perhaps encourage a more optimistic future outlook.

CONCLUSION

The often measured efficacy criteria's of HIV therapy lacks the patient personal perspective which is measured as HRQoL, which if added signifies a holistic approach toward the disease process. Our finding reinforce the fact that patients observation of their quality of life is correlated to their capability to function in society and their ability to do well in daily living proceedings. In our study, we highly recommend focusing on counseling that may be able to improve awareness in tribal resource restricted population.

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