

Research article

Health related quality of life of people living with HIV/AIDS on 2nd line Anti Retroviral Therapy (ART)

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Abstract

Background: HIV/AIDS is a fast spreading communicable disease and management of the disease has its own challenges. The current treatment strategies are based on 2nd line ART and considering the duration of the illness and risk of several other opportunistic infections, the health related quality of life is a major concern. We aimed to assess the HRQOL among the HIV/AIDS patients on 2nd line ART. **Methods:** This study was carried out as a cross sectional study among 334 adults visiting the ART center at Chennai. WHOQOL-BREF questionnaire was used to assess the health related quality of life. Statistical analysis was carried out using SPSS version 16 software. **Results:** The mean age of the study participants was 40.3 years. In this study, 6.9% were separated and 36.2% belonged to upper lower socioeconomic class. The mean score of QOL was highest for the spiritual domain, being 85.14, while the lowest score was observed with social relationship. **Conclusion:** This study elucidates the importance of social and societal component in the management of HIV/AIDS. The management of the disease should stress further on creating awareness and counseling, to not only the PLHAs but also to their first circle of family/ friends in order to improve their quality of life.

Introduction

In India HIV/AIDS is moving from high risk group to the vulnerable segments of the general population. With more than 23.9 lakh people living with HIV/AIDS and an adult prevalence of 0.31% India has the 3rd highest number of people living with HIV/AIDS [1].

HIV/AIDS is a chronic disease. Its management has been a dynamic process with changes in treatment strategies based on sound scientific principles supported by political will and international commitment. HIV management should aim not merely at improving longevity or survival rates but at improving the quality of life. Keeping this in mind Millennium Development Goal 2000 identified combating HIV/AIDS along with other diseases as one of the important goals.

The call to Action at the UN general assembly's special session on HIV/AIDS pushed forward a new global consensus on the need for Anti-retroviral therapy. WHO declared the lack of access to Anti-retroviral treatment for HIV/AIDS a 'Global Health Emergency' in September 2003 and announced that it would release an emergency plan to scale up access to antiretroviral treatment for at least 3 million people by the end of 2005 (popularly known as 3 by 5 initiative). In July 2005, G8 leaders also made a commitment to develop and implement a package for comprehensive HIV prevention, treatment and care,

with the aim to achieve universal access to treatment for all people who need it by 2010. In India the standard anti-retroviral treatment was available through the government sponsored hospitals from 2004.

Failure to the first line drugs made the programme implementers to shift these patients to second line drugs as per national and international guidelines and thus 2nd line ART was launched in India in 2008. Patients whose treatment failed with first line ART would have experienced morbidity. This would have affected the quality of life adversely. Though there are studies on quality of life of PLHAs on first line ART, it becomes important at this juncture to study the quality of life of PLHAs on second line ART. Improvement in life expectancy for people living with HIV and AIDS has resulted in greater emphasis on ways to improve quality of life. As a result of increasing longevity, PLHAs have to deal with more than just disease-related 3 morbidities, such as side effects of drugs, social challenges, psychological and economic stress. One way of capturing personal and social context of patients is to use quality of life measures. Quality of Life is associated with education, income, occupation, family support and clinical categories of the patients [5]. Quality of life is a complex construct which is difficult to assess and interpret. The quality of life scores provide useful denominator for comparison of treatment modalities and

also assesses the impact of treatment on patients. They also provide clues to programme managers for packaging the treatment plan better. HIV/AIDS has a huge impact on the economic status of the individual and family. It affects production as well as household income and expenditure. Beyond the direct cost of medication, monitoring and medical care, indirect cost include the long term lost earnings of HIV infected individuals as well as of their household members who also provide care.

Objectives

To assess the health related quality of life among PLHAs on 2nd line ART.

Methodology

Study design

This study was carried out as a cross sectional study.

Study area

Govt. Hospital for Thoracic Medicine (GHTM), is the largest AIDS care centre in India with around 300 HIV patients visiting the separate HIV OP department daily and over 300 patients taking in-patient treatment in eight exclusive HIV wards. This premier regional institute of the country, serving AIDS patients not just from Tamil Nadu, but also from the entire South India, is recognized by the National AIDS Control Organization as a nodal body involved in all aspects of HIV/AIDS care and support, training and research, voluntary counseling and testing, diagnosis, prophylaxis and treatment of opportunistic infections and delivery of antiretroviral therapy across all sections and sub groups of patients [2].

Study population

All adult patients, who have completed one month of 2nd line ART at GHTM, Tambaram, were included for the study. At GHTM, Tambaram, patients who have failed on 1st line treatment were started on 2nd line ART as per National AIDS Control Organization criteria [3].

Study period

The data was collected during the period from July 2010 to December 2010.

Inclusion criteria

Patients of both sexes

Patients admitted in the hospital and/or those attending the hospital as an outpatient were included for the study.

Patients who had completed one month of 2nd line ART.

Exclusion criteria

Patients on 1st line ART

The patients who did not give consent to participate in the study.

Seriously ill patients

Sample size

There were 334 patients on 2nd line ART attending the GHTM, Tambaram center. All of them were included in the study. A total of 334 patients participated in the study.

Data collection tools

Health related Quality of Life of People Living with HIV/AIDS was assessed using WHO-HIVQOL-BREF Questionnaire. The questionnaire consists of 31 items grouped under six domains namely Physical health, Psychological well-being, Level of Independence, Social relationship, Environmental and Spiritual or Personal beliefs.

Physical domain: Energy, fatigue, pain, discomfort, sleep and rest were included in Physical domain.

Psychological domain: Bodily image, appearance, negative feelings, positive feelings, self-esteem, thinking, learning, memory and concentration were included in Psychological domain.

Level of independence: Mobility, activities of daily living, dependence on medicinal substances and medical aids and work capacity were included in Level of Independence.

Social relationships: Personal relationships, social support and sexual activity were included in Social Relationship.

Environmental domain: Financial resources, freedom, physical safety and security, health and social care, home environment, opportunities for acquiring new information and skills, opportunities for recreation/ leisure, physical environment (pollution/noise/ traffic/climate) and transport were included in Environmental domain.

Spiritual domain: Religion /Spirituality/Personal beliefs were included in Spirituality domain.

There are 31 items, representing the 30 facets. Five of these facets are specific to HIV/AIDS. Individual items are rated on a 5 point Likert scale. The domains mean score was calculated for 100 scales using the Syntax file that checks, recodes data and computes domain scores. Validated version of the WHO-HIV-QOL-BREF is available in four local languages. Validated Tamil version of the questionnaire was used for this study.

Ethical committee approval and informed consent

Permissions were obtained from the Institutional Ethics Committee of our college and also GHTM, Tambaram, Department of Health & Family welfare and also from Kilpauk Medical College, prior to the commencement of data collection. Informed consent was obtained in Tamil

from all the participants prior to the commencement of the study.

Pilot testing

Pilot testing was conducted with 10 patients at GHTM, Tambaram, before starting the main study. Based on the pilot study results, the questionnaire was modified accordingly. The results of the pilot study are not included in the analysis.

Statistical analysis

Data Entry and Analysis was done using SPSSver 16.0 software. The mean and standard deviation of the domain score of different aspects of quality of life were calculated. One way ANOVA was done to compare the mean domain score with age, sex and sex according to the age group. The different levels of quality of life; good, moderate and poor was compared with age, sex, social economic status, marital status and the duration of patients on 2nd line ART.

Result and Discussion

This study was carried out among 334 PHLAs attending GHTM, Tambaram who are on 2nd line ART. The mean age was 40.3 years, with standard deviation of 6.9 years. More than half of the study subjects (77.8%) were in the most economically productive age group of 25 to 45 years, followed by 19.8% in more than 45 years age group. The youngest in the study group was 14 years and the oldest was 63 years. Males constituted 79.3 % of the study group (Figure 1).

Among the study group 68.3 % were married, 13.8 % were widowed due to HIV/AIDS, and 6.9 % were separated due to the stigma and discrimination attached to the disease (Table 1).

Nuclear family was the predominant family type(74 %), while 6.6 % were living alone without any family support. Majority of the study subjects were Hindus (90.7%). More than half (57.8 %) were living in urban area of Tamil Nadu, Andhra Pradesh and Kerala and 42.2 % were from the rural areas of these states. The above data illustrate the need for starting 2nd line ART was almost similar in urban and rural areas. (Table-1). Among the study population 12.8% were illiterates, 24.6 % had studied till middle school and 27.5 % up to high school. Three fourths (78.7%) of the study population were employed, with 32.8% skilled workers mainly as drivers and 22.5% unskilled workers mainly as agricultural labourers (Table 1).

In the study population, 36.2% belonged to upper lower class according to Modified Prasad's socio economic classification. The Upper middle and Lower middle classes had almost equal distribution. 15.8% were in economically weaker section with per capita income of less than Rs. 600 per month (Table 1).

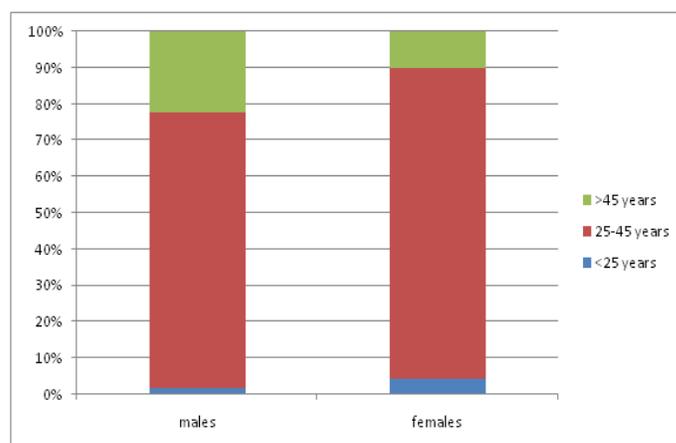


Figure 1. Age and Sex distribution

Table 1. Demographic characteristics

Sr. No	Characteristic	Frequency (n=334)	Percentage
1	Marital status		
	Unmarried	37	11
	Married	228	68.3
	Widowhood	46	13.8
2	Type of Family		
	Separated	23	6.9
	Living alone	22	6.6
3	Religion		
	Nuclear	247	74
	Joint	65	19.4
4	Place of Living		
	Hindu	303	90.7
	Muslim	17	5.1
5	Educational status		
	Christian	14	4.2
	Rural	141	42.2
6	Occupation		
	Urban	193	57.8
	Illiterate	43	12.8
	Primary	45	13.5
	Middle school	82	24.6
	High school	92	27.5
	Higher secondary	41	12.3
7	Socio Economic Class		
	Graduate	24	7.2
	Post Graduate	7	2.1
	Unemployed	71	21.3
	Unskilled	75	22.5
	Semiskilled	50	15
	Skilled	110	32.8
7	Socio Economic Class		
	Semi professional	28	8.4
	Upper Class	25	7.5
	Upper Middle	64	19.2
	Lower Middle	71	21.3
	Upper Lower	121	36.2
	Lower	53	15.8

Anti-retroviral treatment

Among the study group of 334 patients on 2nd line ART, 77.5% had a baseline CD4 count less than 200 cells. When CD4 count dropped the cell mediated immunity fails leading to clinical failure. The mean baseline CD4 counts during initiation of 2nd line ART were 151 cells/cubic. mm with a range of 1 to 841 cells (Table 2).

As per National AIDS Control Organization's, 2nd line ART guidelines the criteria for initiating 2nd line ART were (a) Clinical failure: Occurrence of new OI or malignancy signifying clinical disease progression, onset or recurrence of WHO stage III conditions (b) Immunological failure: Fall of CD4 count to pre-ART therapy baseline without other concomitant infection to explain transient CD4 count decrease, >50% fall from on-treatment peak value, persistent CD4 count level <100 cells/cubic mm.

As per the above criteria, the most common reason for initiating 2nd line ART (94.3%) was OI's stage IV clinical failure. The next reason (12.3%) was fall of CD4 count > 50% from on-treatment peak value. (Table 2).

In the study group of 334 study subjects, the mean duration of patients on 2nd line ART was 12.9 months (Range 1 to 59 months). About half of the study subjects (45.8%) were on 2nd line ART for 6 -24 months. (Table 2)

Stigma and discrimination

Disclosure of HIV status by the study subjects to the spouse was to the extent of 81.7%, to siblings was 26%, to other family members 73.1%, to friends/relatives 23.1% and to primary medical care givers 36.8%. The study subjects had disclosed their HIV status to more than one of the above categories. The study subjects were discriminated mainly by HIV negative spouse. (13.2%). (Table 3).

Table 2. Details of ART treatment

Sr. No	Particulars	Frequency (n=334)	Percentage
1	Baseline CD4 count		
	< 200 CD4 cells	259	77.5
	200 to 350 CD4 cells	31	9.3
	>350 CD4 cells	44	13.2
2	Reasons for initiating 2nd line ART*		
	CD4 < baseline value	28	8.4
	CD4 not crossed 100 even after 1 year of 1st line ART	1	0.3
	Fall of CD4 >50% from peak value	41	12.3
	OIs stage IV clinical failure	315	94.3
3	Duration of 2nd line ART		
	<6 months	131	39.2
	6 to 24 months	153	45.8
	>24 months	50	15

*total will not be equal to 334.

Table 3. Disclosure and Discrimination of HIV status

Sr. No	Relationship	Awareness (%)	Discriminated (%)
1	Spouse	273 (81.7)	36(13.2)
2	Siblings	87 (26)	10 (11.5)
3	Other Family members	244 (73.1)	18 (7.4)
4	Relatives & Friends	77 (23.1)	14 (18.2)
5	Work place	42 (12.6)	4 (3.3)
6	Hospital	123 (36.8)	4 (3.3)

Participation in social activities

Out of 334 study subjects, (77.8%) did not have any issues in taking part in social activities like relatives' marriages, rituals etc., as before whereas 22.2% responded that they were restricting themselves from taking part in social activities.

Majority of the study subjects, (79%) were satisfied with the 2nd line ART drugs supplied under Government ART programme, because of the good quality of drugs and clinical improvement in the condition of the study subjects. Only very few (1.2%) were dissatisfied due to opportunistic infections like CMV retinitis and other ailments like paraplegia. (Table 4). Out of 334 study subjects 36.5% wanted to continue treatment at GHTM, Tambaram, and the rest 63.5% did not want to continue at GHTM, Tambaram. Although 79% of the study subjects were satisfied with 2nd line anti-retro viral treatment, they were finding it difficult to come to GHTM, Tambaram as it was far from their residence.

The mean distance travelled by the study group was 302.9 kilometers and 41.6% of the study subjects had to travel 300-500 kilometers to access the 2nd line ART drugs at GHTM, Tambaram. Among the study subjects, 32 had travelled less than 20 kilometers. (Table 4).

Table 4. Opinion regarding 2nd line anti-retro viral treatment

S. No	Particulars	Frequency	Percentage
1	Opinion regarding 2nd line ART*		
	Very Dissatisfied	2	0.6
	Dissatisfied	2	0.6
	Neither satisfied nor dissatisfied	19	5.7
	Satisfied	264	79
	Very Satisfied	47	14.1
2	Distance travelled for ART		
	< 100 kms	64	19.2
	100 to 300 kms	93	27.8
	300 to 500 kms	139	41.6
	500 to 700 kms	37	11.1
	> 700 kms	1	0.3

*total will not be 334.

WHO Health Related HIVQOL –Domain Scores

In the study group of 334, the quality of life was assessed by WHO HIV QOL BREF, and the domain scores were analyzed under the following headings. The mean score of the spiritual domain was highest to the extent of 85.14 with standard deviation of 13.4, followed by the physical domain with a mean score of 73.30 with standard deviation of 15.8. The lowest domains mean score was 30.26 with standard deviation of 20.2 for the domain social relationship. This low mean score in the domain social relationship indicates that there is stigma and discrimination against the disease HIV/AIDS (Table 5).

The mean domain score was higher for men as compared to women in all the domains and this difference is found to be statistically significant indicating that men experienced better quality of life compared to women in all domains (Table 6).

The spiritual domain had significantly higher quality of life in the younger age group women as compared to men. Whereas the social relationship and environmental domains also had higher quality of life in younger age group women as compared to men but it was not statistically significant. However in the higher age groups men had significantly higher quality of life in all the domains (Table 7).

Among the study subject of 334, the mean domain score was calculated as per the guidelines given in WHO HIV QOL manual 18. For a better understanding, the domain score was analyzed arbitrarily in three different levels of mean score as poor, moderate and good. The poor quality of life includes less than 30 percent of each domain scores, the moderate quality of life includes 30 to 60 percent of each domain scores and the good quality of life indicates more than 60 percent of the domain scores. The analysis shows that 92.8% have good spiritual quality of life, 86.8% have good quality of life in terms of level of independence, 83.5% have good physical quality of life, 72.2% have a good quality of life in psychological aspects, and 60.2% of the study subjects have good

quality of life in terms of environmental factors. In contrast, 50.3% of the study subjects have got a poor quality of life in terms of social relationship. (Table 8).

The level of quality of life was compared in different age groups. Overall, 100% of the younger age group (less than 25 years) were having a good spiritual quality of life, the next level of quality of life in terms of level of independence was 88.1% in the economically productive age group of 25-45 years. Poor quality of life was experienced by 62.5% of the younger age group and 50.8% of the economically productive age group for social relationship. The differences in the levels of quality of life were found to be statistically significant ($p=0.007$). Details are given in Table 9.

Comparison between socio economic class and the quality of life was done. The analysis showed 98.4% were showing good spiritual quality of life. All the socioeconomic classes experienced good psychological quality of life and this was maximum (84%) in the upper class. The difference in the level of quality of life was found to be statistically significant ($p=0.0001$). All the socioeconomic classes experienced good quality of life in terms of level of independence and this was maximum (95.3%) in the upper middle class. The difference in the level of quality of life was found to be statistically significant ($p=0.004$). All the socio economic classes experienced poor quality of life for social relationship.

Table 5. Domain mean scores of quality of life

Sr. No	Domain	Mean Score	Standard Deviation
1	Physical	73.3	15.8
2	Psychological	69.54	14.3
3	Level of Independence	72.1	15.3
4	Social Relationship	30.26	20.2
5	Environmental	64.39	13.1
6	Spiritual	85.14	13.4

Table 6. Comparison between Domains mean scores and sex of the Individual.

Sr. No	Domain	Sex	N	Mean	S.D	P value
1	Physical	Male	265	74.83	15.6	0.0001
		Female	69	67.39	15.2	
2	Psychological	Male	265	70.94	13.5	0.00001
		Female	69	64.13	16	
3	Level of independence	Male	265	73.51	14.7	0.001
		Female	69	66.67	16.5	
4	Social Relationship	Male	265	31.42	20.5	0.04
		Female	69	25.81	18.8	
6	Environmental	Male	265	65.87	12.4	0.0001
		Female	69	58.7	14.3	
7	Spiritual	Male	265	86.3	12.3	0.002
		Female	69	80.71	16.6	

Table 7. Comparison between Domains mean scores and sex in different age groups

Sr. No.	Domain	Age in years	Sex	N	Mean	SD	P value
1	Physical	<25	Male	5	71.3	22.4	0.531
			Female	3	81.3	16.5	
		25-45	Male	201	75.2	15.7	0.003
			Female	59	68.4	14	
		>45	Male	59	73.8	14.7	0.001
			Female	7	52.7	15.7	
2	Psychological	<25	Male	5	69	13.9	0.204
			Female	3	85	18	
		25-45	Male	201	70.6	13.4	0.001
			Female	59	64	14.7	
		>45	Male	59	72.2	14.1	0.01
			Female	7	56.4	20.4	
3	Level of Independence	<25	Male	5	75	15.3	0.717
			Female	3	81.3	32.5	
		25-45	Male	201	73.5	14.2	0.007
			Female	59	67.8	14.1	
		>45	Male	59	73.5	16.5	0.001
			Female	7	50.9	19.2	
4	Social	<25	Male	5	31.3	29	0.569
			Female	3	45.8	40.2	
		25-45	Male	201	31.3	18.8	0.046
			Female	59	25.7	17.7	
		>45	Male	59	32	25.2	0.15
			Female	7	17.9	12.2	
5	Environmental	<25	Male	5	65	18.5	0.33
			Female	3	79.2	17.7	
		25-45	Male	201	65.4	11.7	0.0001
			Female	59	58.5	13.6	
		>45	Male	59	67.6	14.1	0.006
			Female	7	51.8	12.9	
6	Spiritual	<25	Male	5	87.5	6.3	0.041
			Female	3	97.9	3.6	
		25-45	Male	201	85.7	13.1	0.017
			Female	59	80.8	15.8	
		>45	Male	59	88.1	9.2	0.001
			Female	7	72.3	22.2	

Table 8: Level of quality of life based on domain scores

S. N.	Domain	Poor (%)	Moderate (%)	Good (%)
1	Physical	1.5	15	83.5
2	Psychological	0.9	26.9	72.2
3	Level of Independence	2.4	10.8	86.8
4	Social Relationship	50.3	41.3	8.4
5	Environmental	0	39.8	60.2
6	Spiritual	0.6	6.6	92.8

This was worst for the lower class (60.4%). The difference in the level of quality of life was found to be statistically significant ($p=0.0001$). Good quality of life in terms of environment was experienced by upper (92%), upper middle (79.7) and lower middle (64.8%) classes. The upper lower (50.4%) and lower class (60.4%) experienced moderate quality of life. The difference in

the level of quality of life was found to be statistically significant ($p=0.0001$). Details are given in Table 10.

Discussion

This study has highlighted the health related quality of life of people living with HIV/AIDS on 2nd line anti-retroviral treatment at Government hospital for thoracic medicine, Tambaram.

Second line anti-retroviral treatment was started from 28th January 2008, at GHTM, Tambaram. Till the end of the study period (December 2010) 334 adult HIV/AIDS patients were registered for 2nd line ART at GHTM, Tambaram. All the 334 adult 2nd line ART patients were included in the study. All of them were eligible for the study as per eligibility criteria. The patients were from Tamil Nadu and the neighbouring states of Andhra Pradesh and Kerala, as GHTM, Tambaram was the designated centre of excellence for 2nd line anti-retroviral treatment for these states.

Table 9. Comparison between levels of quality of life and different age groups

Sr. No.	Domain	Age in years	Poor (%)	Moderate (%)	Good (%)	P value
1	Physical	<25*	0	12.5	87.5	0.811
		25-45	1.5	13.8	84.6	
		>45	1.5	19.7	77.8	
2	Psychological	<25*	0	25	75	0.98
		25-45	0.8	26.9	72.3	
		>45	1.5	27.3	71.2	
3	Level of Independence	<25*	0	25	75	0.165
		25-45	1.5	10.4	88.1	
		>45	6.1	10.6	83.3	
4	Social	<25*	62.5	0	37.5	0.0007
		25-45	50.8	42.7	6.5	
		>45	47	40.9	12.1	
5	Environmental	<25*	0	50	50	0.701
		25-45	0	40.4	59.6	
		>45	0	36.4	63.6	
6	Spiritual	<25*	0	0	100	0.766
		25-45	0.8	7.3	91.9	
		>45	0	4.5	95.5	

Table 10: Comparison between Socio Economic Class and level of quality of Life

Sr. No.	Domain	Socio Economic Class	Poor(%)	Moderate(%)	Good(%)	P value
1	Physical	Upper	4.0	8.0	88.0	0.060
		Upper Middle	0.0	12.5	87.5	
		Lower Middle	0.0	11.3	88.7	
		Upper Lower	1.7	14.0	84.3	
		Lower	3.8	28.3	67.9	
2	Psychological	Upper	8.0	8.0	84.0	0.0001
		Upper Middle	0.0	20.3	79.7	
		Lower Middle	0.0	22.5	77.5	
		Upper Lower	0.8	29.8	69.4	
		Lower	0.0	43.4	56.6	
3	Level of Independence	Upper	4.0	12.0	84.0	0.004
		Upper Middle	1.6	3.1	95.3	
		Lower Middle	1.4	7.0	91.5	
		Upper Lower	1.7	9.9	88.4	
		Lower	5.7	26.4	67.9	
4	Social	Upper	36.0	32.0	32.0	0.0001
		Upper Middle	37.5	54.7	7.8	
		Lower Middle	45.0	46.5	8.5	
		Upper Lower	58.6	36.4	5.0	
		Lower	60.4	34.0	5.6	
5	Environmental	Upper	0.0	8.0	92.0	0.0001
		Upper Middle	0.0	20.3	79.7	
		Lower Middle	0.0	35.2	64.8	
		Upper Lower	0.0	50.4	49.6	
		Lower	0.0	60.4	39.6	
6	Spiritual	Upper	4.0	12.0	84.0	0.213
		Upper Middle	0.0	1.6	98.4	
		Lower Middle	0.0	5.6	94.4	
		Upper Lower	0.8	8.3	90.9	
		Lower	0.0	7.5	92.5	

First line anti-retroviral treatment was started in 2004 in India. Researchers and policy makers were interested in knowing its effects and many studies came up comparing the quality of life in symptomatic and asymptomatic and those on anti-retroviral treatment and those only on OI prophylaxis. Similarly studies on quality of life came up from other developing countries too. All these studies showed that ART produced a definite improvement in quality of life of HIV infected people.

After four years of NRTI and NNRTI based first line anti-retroviral regimens, immunological and virological failures were encountered as evidenced by the following predictor studies. In Uganda, 36% phenotypic drug resistance was reported among patients in an ART program [7]. Euro SIDA, a prospective, international, observational cohort study of HIV-infected patients in Europe, reported the incidence of treatment failure at 12 months as 11.6 per 100 person-years [8]. A study done by Rajesekaran et al in 2007 predicted that the need for 2nd line ART would be significant in India (approximately 51,000) therefore, developing appropriate policy for second-line treatment was needed [9]. More effective protease inhibitors based regimens which have lesser adverse effects were introduced though they were expensive than the first line regimen. As we walk along in time with the PLHAs; in the pre ART phase the PLHAs were depressed and panicked as the only management possible was OI prophylaxis. There was no standard treatment available for HIV and stigma was high. This cost them their job and status in the family. At this point the PLHAs were a psychologically, economically and socially deprived community. The quality of life as proved by the studies was very less [10, 4, 11]. NACO's priorities were to create awareness as this controlled the spread of the disease and reduced stigma.

Non-governmental organisations and positive networks helped PLHAs by guiding them for treatment and providing financial assistance in the form of flexi loans to stabilize them economically. Introduction of ART brought hope in the lives of PLHAs and the quality of life improved. Then came the concept of living with AIDS where counseling had a major role in highlighting the importance of adherence to treatment and motivating PLHAs to live a normal life.

ART was initially available only in centres where care and support was available. As awareness improved, treatment regimens standardized and rights of HIV patients realized ART became available in tertiary care centres and district level hospitals in a phased manner. All these factors led to the perception of HIV as a chronic disease. HIV which was a disease of certain occupational groups (truck drivers and migrant labours) moved into the general population as evidenced by the 2009 sentinel surveillance report.

As longevity of the PLHA's increased, NACO strengthened the care and support centres, PPTCT was

recognized to be a key intervention in prevention, the need to improve the surveillance system was realised and vaccine trials done.

As per the results of this study, first line ART failure was encountered after a period of one to nine years. These patients were once again faced with depression and panic regarding future. The vicious cycle of OIs, pain, disfigurement, decreased capacity to work, loss of job and stigma re-emerged. Caregivers were not trained in 2nd line ART and protease inhibitors were expensive and no better alternative was available. In a measure to conserve its usage to those who definitely need it, alternative first line ART was given. When first line ART was introduced, it was initiated in patients whose CD4 count was less than 200 cells per cubic mm. The response was slow and poor. CD4 count took longer to recover and IRIS complications were more. Hence, ART was initiated when CD4 count dropped below 350 cells per cubic mm.

To address all these issues in introducing 2nd line ART, NACO identified ten centres of excellence which had facilities for care and support, palliative care and expertise in management. One such centre is GHTM, Tambaram. SACEP is a committee where each case of failure is discussed and examined if the case qualifies for 2nd line ART.

At this juncture with 3 years and almost 2000 patients on 2nd line ART there are no published data on quality of life of people living with HIV/AIDS on 2nd line ART. Is 2nd line ART effective in addressing pain, bodily image, social acceptance, working capacity and boosting confidence of PLHA's and are policy makers justified in incorporating this expensive treatment regimen are questions that need to be answered.

For assessing quality of life the WHO QOL is a questionnaire with 120 questions. The WHO QOL BREF has 26 questions under 4 domains. The WHO QOL HIV BREF is specific for HIV with 31 questions under 6 domains. There are not many studies published using this questionnaire. The studies done so far used mean score of all the domains which is not an appropriate method. None of them have demarcated quality of life as good or bad. This study has attempted for the first time to classify the quality of life as good, moderate and poor using the WHO-HIV-QOL-BREF questionnaire.

The results of this study showed that there are more men than women and 74% were living in nuclear family setup. The sole bread winner's quality of life has a bearing on the family's level of living and it is important that the quality of life is good for the economically productive person. The educational status of the participants is at or below middle school level and most of them are skilled or unskilled labourers. Physical quality of life and capacity to work have to be good to sustain them in their jobs.

Even after 25 years of existence of the disease, awareness generation and de-stigmatization efforts of the programme, positive networks and non-governmental

organizations fighting for the rights of PLHAs, HIV having moved from high risk to general population and HIV being considered as a chronic disease, stigma and discrimination still exist. The results of this study showed that HIV status disclosure is far from 100%. HIV disclosure is 23% to friends and relatives and only 12% in work place. Discrimination in work place was perceived by 33% of participants. PLHAs have a number of woes related to work. Some have to quit their job because of their status, shift from permanent to temporary jobs because of sickness spells, move down from skilled to unskilled jobs, avail leave or absent from duty to access health care and worst of all face discrimination at work place. Although after 2nd line anti-retroviral treatment, PLHAs are able to lead a socially acceptable life, 22% of the study participants were hesitating to take part in social activities probably for the fear of being discriminated. These factors are reflected in low social quality of life seen in this study.

Since this study was done on 2nd line anti-retroviral treatment and data on OIs and complications during their first line ART were available it was possible to calculate for how long a patient can be on 1st line anti-retroviral treatment free from OIs and complications. The mean duration was 2.8 years with a minimum one year to a maximum of nine years. This was possible because of good adherence level as a result of repeated counseling. Since the current need for 1st line ART is high, we can expect an increased case load on 2nd line anti-retroviral treatment in future.

Failure results from drug resistance and decreasing response to treatment. NACO in line with WHO's recommendations has fixed criteria for identifying patients for 2nd line anti-retroviral treatment. CD4 cell counter is now accessible for all the ART centres. Viral load assays are very sensitive and pick up treatment failure earlier than clinical recognition.

In this study 2nd line ART was started in 94.3% of cases for stage IV clinical disease and OI. This was found to be the most common reason for referral to SACEP committee. Though the study finding highlights the clinical expertise of ART medical officers in identifying failure and emphasizes the importance of continuous training for care givers, programme has to address the issue of accessibility of viral cell counter before decentralization of 2nd line ART programme.

Although the eligibility criterion for this study was to include patients on 2nd line ART for more than one month, about 61% of the subjects had received 2nd line ART for more than six months. Assessing the quality of life at this stage will be more meaningful. The mean score in descending order for the various domains is 85.14 for spiritual, 73.30 for physical, 72.10 for level of independence, 69.54 for psychological, 64.39 for environmental and 30.26 for social domains.

In this study the quality of life in spiritual domain had maximum score of 85.14 which reflects that the subjects did not fear death and found purpose and meaning in life. This is probably due to the coping skills given by our culture supported by religious beliefs. Next in line was the quality of life in physical domain with a mean score of 73.3. This reflects that patients did not perceive pain, had good energy levels and had adequate sleep. Most probably this could be attributed to 2nd line ART, good nutrition and healthy lifestyle.

In the quality of life the domain which showed very low level was the social relationship domain. This reflects the personal relationship, social support and sexual relationship. For the fear of spread of disease most of the study subjects had to compromise their sexual relationship. This is one of the main reasons for low scores in this domain. In the Delhi study which was on HIV positive individuals the mean score in this domain was high. The probable reason could be that in early stages of the disease there was not much awareness about the spread of the disease where sexual relationship was unrestricted among the individuals. With growing knowledge about the disease it was learned that sexual contact between two HIV positive individuals can lead to spread of mutagenic virus which could be drug resistant. So, PLHAs were counseled for restricted and safe sex even with a HIV positive spouse/ partner.

When compared to the first line ART studies, this study showed a markedly increased mean domain score of 64.39 in the environment domain. This suggests that patients had better quality and access to health care. The mean score of quality of life in the level of independence was 72.1. This reflects good mobility, good performance of activity of living and that capacity to work had increased.

This study corroborates with the findings of other studies that there is a significantly higher quality of life for men as compared to women [12, 13, and 14]. This is a result probably of low social status and literacy of women. The low physical quality of life is probably because of poor health seeking behavior, poor nutrition as men get preference for food. Women worry about the future of the family and have more negative feelings like despair, anxiety and depression which results in low psychological quality of life. Emotional disturbances are more prevalent among women [15].

The quality of life for level of independence is low probably because of their restricted mobility as they have lower literacy levels and are dependent on others to travel for to accessing health care. The decreased physical strength leads to decreased capacity to work.

The quality of life with respect to social relationship is also low in women, worse than men as social acceptance of the disease is better for men. Women have restricted social contacts and do not access the social support networks like men. A south Indian study showed that

women had to face non-consensual sex, sexual violence and were unable to refuse husbands sexual demands [16-18]. Gender and economic inequalities, implicated in marital violence also contribute to women's low social quality of life [19]. The spiritual domain had a significantly higher quality of life in the younger age group women as compared to men. The social and environmental domains also had higher quality of life in this age group woman as compared to men but it was not statistically significant. However, in the higher age groups men had significantly higher quality of life in all the domains.

Mere increase in longevity without improving quality of life only adds to the burden that women face. Programme should envisage interventions which examine reasons and offer solutions for quality of life improvement in women. Mental health assessment and management of depression should be a part of the intervention.

Unmarried or marital separated subjects had quality of life scores in the good category in all but physical domain. The probable reasons could be lesser family responsibilities, no restrictions on mobility and undivided earnings. They probably also had no fear of death and no fear of leaving behind orphans. Married individuals who had good family support during illness had good quality of life in physical domain. This is similar to other studies [06]. Married individuals had lower proportion perceiving good environmental quality of life as compared to unmarried and separated ones. This is in contrary to other studies [10]. Widowed individuals had the worst quality of life. The finding that unmarried and martially separated individuals enjoyed better quality of life than those with a family stresses the importance of family counseling.

In this study there were significantly higher proportions of quality of life in the good category in psychological, environmental and level of independence domains for the upper and upper middle class. There was a linear relationship between good quality of life and socio economic class as in other studies [11, 20]. There should be focused interventions targeting the low socio economic class like poverty alleviation programmes, non-governmental organizations and positive network supporting the low socio economic groups and subsidizing incremental costs like travel concession. Programmes for promoting free education for children of HIV positive parents should be available.

Quality of life was in the good category in physical, psychological, level of independence and spiritual domains within six months of starting 2nd line ART. After first line ART failure there was no other alternative treatment available other than 2nd line ART. At this point, the patient's first priority was health. Hence there was appreciable increase in quality of life scores in afore said domains. As the duration of treatment increased, probably the patient's ailments decreased and priorities shifted from health to continuance in job, family responsibilities,

family security etc. One who was playing sickness role started playing a normal person role as time progressed. Although this is the trend seen in chronic diseases, the patients' attitude towards the disease and health seeking behaviour should not dilute as time progressed.

According to this study patients developed failure after a mean 2.8 years on first line ART. Once they have been started on 2nd line ART next, option is not available as of now if 2nd line ART fails. There are no vaccines available at present. The programme should ensure that adherence is almost hundred percent and patients do not miss even a single dose. This can be done by increasing accessibility of 2nd line ART. The study advocates the government's policy to train all ART medical officers in 2nd line ART and standardize the criteria for enrolling the patients. Undiluted and uncompromised decentralizing in a phased manner to tertiary care centres and then to district hospitals, as the study shows that there was almost equal proportions of patients from both urban and rural areas is the need of the hour.

Conclusion

This study gave an opportunity to look at second line ART delivery from the patient's perspective. The benefits patients have derived will help the programme managers take it one step closer to them and knowledge of the difficulties they encounter will give the programme managers an insight to address them.

Anti-retroviral treatment has improved the quality of life of people living with HIV/AIDS. Second line ART has also improved the overall quality of life of people living with HIV/AIDS in all except the social relationship domain. Regular treatment should be able to sustain this level of quality of life and probably improve it further.

The study recommends that women PLHAs should be given more attention in terms of counseling, care and support since the quality of life was found lower in all the domains compared to men PLHAs. The study recommends more emphasizes on family counseling since the quality of life is lower for married subjects.

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