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An investigation into the health-related quality of life of individuals living with HIV who are receiving HAART

J. JELSMA[1], E. MACLEAN[2], J. HUGHES[1], X. TINISE[2], & M. DARDER[2]

[1]*Department of Health and Rehabilitation Sciences, Faculty of Health Sciences, University of Cape Town, and* [2]*Médecins Sans Frontières, Cape Town, South Africa*

Abstract

The health authorities have recently accepted the routine provision of highly active antiretroviral therapy to persons living with AIDS in South Africa. There is a need to investigate the impact of HAART on the health-related quality of life of people living with HIV/AIDS (PLWHA) in a resource-poor environment, as this will have an influence on compliance and treatment outcome. The aim of this study was to explore whether HAART is efficacious in improving the self-reported health-related quality of life (HRQoL) in a group of PWLA in WHO Stages 3 and 4 living in a resource-poor community. A quasi-experimental, prospective repeated measures design was used to monitor the HRQoL over time in participants recruited to an existing HAART programme. The HRQoL of 117 participants was determined through the use of the Xhosa version of the EQ-5D and measurements were taken at baseline, one, six and 12 months. At the time of the 12-month questionnaire, 95 participants had been on HAART for 12 months. Not all participants attended all follow-up visits, but only two participants had withdrawn from the HAART programme, after two or three months. At baseline, the rank order of problems reported in all domains of the EQ-5D was significantly greater than at 12 months. The mean score on the global rating of health status increased significantly ($p < 0.001$) from a mean of 61.7 (SD = 22.7) at baseline to 76.1 at 12 months (SD = 18.5) It is concluded that, even in a resource-poor environment, HRQoL can be greatly improved by HAART, and that the possible side effects of the drugs seem to have a negligible impact on the wellbeing of the subjects. This bodes well for the anticipated roll-out of HAART within the public health sector in South Africa.

Introduction

The HIV/AIDS pandemic has reached catastrophic proportions in sub-Saharan Africa. In 2002, the incidence rate in South Africa was estimated to be 2% and the prevalence rate for the total population to be 14.2% (Dorrington et al., 2002). Projections indicate that, in the absence of antiretroviral treatment, the number of deaths due to AIDS is expected to result in a cumulative total of five to seven million in South Africa by 2010 (Dorrington et al., 2001). A recent survey has indicated that the prevalence of HIV in South Africa is highest in young adults, particularly those living in informal or township settings (Shishana & Simbayi, 2002). In 2002, it was estimated that of those infected in South Africa, 18% were

Correspondence: Jennifer Jelsma, Department of Health and Rehabilitation Sciences, Faculty of Health Sciences, University of Cape Town, Anzio Road, Cape Town, South Africa. South Africa. Tel: +27 (021) 4066402. Fax: +27 (021) 4488157. E-mail: jjelsma@uctgsh1.uct.ac.za

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in the third stage of the disease and 7% were in the final stage of the disease (Dorrington et al., 2002).

In 2002, Cullinan reported that the South African government had taken tentative steps to provide antiretroviral therapy (Cullinan, 2002) and by March 2004, it was in the process of expanding access to HAART within the public sector. However, there was still some concern that the treatment was 'toxic', a legitimate concern, both for the individual who might experience unpleasant side effects and for the community if this leads to non-compliance and drug resistance. One way to detect undesirable side effects of HAART is to monitor the health-related quality of life (HRQoL; Han et al., 2002) of PLWHA who are on treatment. It would be reasonable to expect that, if the toxic effects are significant, PLWHA would experience either maintenance of or a decline in baseline HRQoL and that their HRQoL would remain worse than others living in the same community. In addition, improvements in functional status and wellbeing can be regarded as essential outcomes of the management of chronic diseases (Murri et al., 2003) and as such should be measured regularly.

Health-related quality of life is a multidimensional concept that includes global health perspectives, symptom status, functional status, biological and physical variables, individual and environmental characteristics and general health perceptions (Wilson & Cleary, 1995). There are many different instruments that have been developed to describe and quantify HRQoL. These include HIV-specific instruments such as the Medical Outcomes Study-HIV (Smith et al., 1996), the HIV Overview of Problems-Evaluation System (O'Leary et al., 1998) and the WHOQOL module for international assessment in HIV/AIDS (WHOQOL Group, 2003). The EQ-5D, a generic HRQoL instrument that describes health state in terms of five dimensions (mobility, self-care, usual activities, anxiety/depression and pain/discomfort) (Brooks & EuroQol Group, 1996) has been also used to examine HRQoL in participants with HIV (Badia et al., 1999; Delate & Coons, 1999). Some instruments have specifically been tested in an African context. The SF36 was used to monitor HRQoL in PLWHA in South Africa (O'Keefe & Wood, 1996) and the EQ-5D has been validated in both Zimbabwe (Jelsma et al., 2001) and South Africa (Jelsma et al., 2004). Mast et al. (2004) report that patient-reported measures of HRQoL are likely to be reliable and valid methods of assessing the impact of different HIV/AIDS interventions within an African context.

In 2001, the international humanitarian aid organization, Médecins Sans Frontières, in partnership with the Western Cape Provincial Department of Public Health, began to provide care and treatment to PLWHA in a resource-poor township outside of Cape Town which has a population of about 500,000, an estimated prevalence of 50,000 living with HIV and in 2003, an antenatal prevalence rate of 25%. The details of the programme and the impact on morbidity are described elsewhere (Coetzee et al., 2004). Coetzee et al. documented the effect of the programme on morbidity and the survival rate after 24 months of treatment was reported to be 86.4%, even though more than half had CD4 cell counts of less than 50 at the start of treatment. The intention of the current study was to monitor the HRQoL of the people who participated in this programme.

Aim

The aim of this study was to explore whether HAART was efficacious in improving the self-reported health-related quality of life (HRQoL) in a group of PWLA in WHO Stages 3 and 4 living in a resource-poor community.

The specific objectives of the study were to determine if there was a significant difference in HRQoL between the scores of participants living with HIV/AIDS at baseline, i.e. before initiation of HAART, and 12 months post-initiation. A secondary objective was to describe when, if at all, the HRQoL changed over this 12-month period and whether it improved or deteriorated.

Methods

As the use of a control group would have raised serious ethical concerns, a quasi-experimental, prospective repeated measures design was used to monitor the HRQoL over time in new participants recruited to the MSF programme.

Participants

All participants in this study were receiving HAART through one of the three HIV clinics. The criteria for inclusion on the programme include: (1) clinical criteria (WHO Stages 3 or 4 signifying former or current HIV-related illness, including tuberculosis; CD4 count less than 200/mm^3), (2) social criteria (resident of the area; willingness to attend monthly support group;), and (3) adherence criteria (at least three months of attendance at clinic; prior adherence to TB treatment; selection of a treatment assistant; regularity of clinic visits). All patients on treatment were residents of the same resource-poor area.

Instrumentation

The Xhosa version of the EQ-5D was used. The major advantage of this instrument is that there is a Xhosa version recognized by the EuroQol Group, which was produced by adhering strictly to the official translation protocol (Mkoka et al., 2003). The reliability and validity of the instrument has been established in the population under consideration in the current study. For the above reasons, the EQ-5D was regarded as an appropriate outcome measure for studies with PLWHA whose first language is Xhosa. The health state was described using the five EQ-5D domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The measurement of health status was done using the visual analogue scale, which is incorporated into the EQ-5D, and a utility index calculated using values attributed to the levels of each domain. The instrument was self-administered, although the research assistants gave assistance to the participants who were not literate, a total of nine in all. The administration was standardized through holding a training session and by the fact that only three field workers did all the data collection.

Procedure

Patient recruitment lasted from April to December 2002 and data collection for analysis ended in October 2003. The designated multidisciplinary HIV clinics treat patients who are in the late stages of HIV/AIDS (WHO Stages 3 or 4). The programme was ongoing at the time of writing. Clients attending the HIV clinics who were determined to be eligible for HAART by clinical, biological, adherence and social criteria were presented to a community selection committee. Those approved by the selection committee returned to the clinic to discuss the implications of HAART with their counsellor and doctor. At this visit, they received a detailed consent form to participate in the HAART programme. They

returned to the clinic, generally within two weeks, to sign the consent form and begin receiving HAART.

At this visit, immediately prior to the initiation of HAART, clients were asked if they would be willing to participate in the HRQoL study and other studies, including documentation of compliance (Darder et al., 2003) and the economic impact of HIV/AIDS (to be published elsewhere). For clients that agreed, informed consent was obtained and the baseline EQ-5D measure was taken. These clients were followed-up at one, three, six and 12 months following initiation of HAART. Participants who did not attend the clinic were followed-up by the interviewers and counsellors to determine the reason for not attending. Six Xhosa-speaking interviewers attended a training session and took part in a pilot project to test the feasibility of the studies. Three were subsequently employed solely to interview clients awaiting their clinical consultation and performed no other functions in the clinics.

Data analysis

Descriptive statistics were used to describe the health states of the participants at each data collection point. The data of participants who died during the course of the study were excluded from analysis as initial inclusion might decrease the mean HRQoL compared to later analysis when their information would be excluded.

In order to restrict the number of tests, only the difference in the rank ordering of the domain scores and between the mean VAS scores at baseline and 12 months were tested using the Wilcoxon sign rank test and paired t-test, respectively. The results at the other time periods were presented graphically.

Ethical considerations

The University of Cape Town Medical Research Ethics Board gave ethical approval. Informed consent was given by the participants separately for participation in the HAART programme and the HRQoL study. HRQoL participation was only requested after clients had already been approved to begin treatment. It was made clear that participation was voluntary and did not affect participation in the HAART programme in any way. Individual results from the study were confidential and not provided to the clinic staff. Interviews were conducted in a private venue with no one present aside from the client and the interviewer.

Results

No recipient of HAART refused to take part in the HRQoL study. An initial 139 participants were recruited, of these 11 never commenced HAART, one moved to Johannesburg and ten died during the course of the study (Table I). The remaining 117

Table I. Attendance of participants at each appointment.

	Baseline	1 month	3 months	6 months	12 months
Attended	95	102	97	98	83
Data missing for this visit	21	15	21	19	13
Eligible for attendance	117	117	117	117	97

Note: Not all participants attended every follow-up visit. Apart from two participants who were lost to follow-up, all participants were still receiving medication at the time of analysis.

constituted the experimental group and, of these, 74.5% were female. Not all of the 117 participants were seen by the research assistants at each visit, due to logistic and administrative problems. At the time of the 12-month questionnaire, 95 participants had been on HAART for 12 months, of which 84 were interviewed. However, with the exception of two participants who had not been interviewed since June, all participants were still receiving HAART at the time of analysis.

Table II depicts the percentage of respondents reporting problems on the five different domains and the mean scores of the values of the health states and the Visual Analogue Scale. The rank order of self-care ($p = 0.031$), usual activities ($p < 0.01$), pain and discomfort ($p < 0.01$) and anxiety/depression ($p = 0.023$) were all significantly different between baseline and 12 months with more people reporting problems, in the baseline scores.

Figures 1 and 2 demonstrate the almost linear improvement in health state from baseline to 12 months, both with regard to the number of participants reporting problems in each

Table II. Scores on the five descriptor domains, the mean values of the health states (calculated using the recommended EQ-5D value set) and the Visual Analogue Scale scores at the different time periods.

	Reference Sample	Baseline	1 month	3 months	6 months	12 months
n	106	95	102	97	98	83
Mobility						
No problems	85.2	73.7	82.4	86.6	83.7	89.2
Some problems	14.8	23.2	16.7	13.4	15.3	10.8
Severe problems	0.0	3.2	1.0	0.0	1.0	0.0
Total	100.0	100.0	100.0	100.0	100.0	100.0
Self-care						
No problems	95.3	90.5	91.2	94.8	100.0	100.0
Some problems	4.7	7.4	8.8	5.2	0.0	0.0
Severe problems	0.0	2.1	0.0	0.0	0.0	0.0
Total	100.0	100.0	100.0	100.0	100.0	100.0
Usual activities						
No problems	89.8	75.8	79.4	87.6	89.8	94.0
Some problems	9.3	15.8	17.6	11.3	9.2	4.8
Severe problems	0.9	8.4	2.9	1.0	1.0	1.2
Total	100.0	100.0	100.0	100.0	100.0	100.0
Pain/discomfort						
No problems	66.7	29.5	45.1	53.6	60.2	73.5
Some problems	25.9	64.2	48.0	44.3	37.8	24.1
Severe problems	7.4	6.3	6.9	2.1	2.0	2.4
Total	100.0	100.0	100.0	100.0	100.0	100.0
Anxiety/depression						
No problems	75.9	68.4	83.3	79.4	82.7	85.5
Some problems	21.3	28.4	16.7	19.6	13.3	13.3
Severe problems	2.8	3.2	0.9	1.0	4.1	1.2
Total	100.0	100.0	100.0	100.0	100.0	100.0
Visual Analogue Scale						
Mean score	80.1	61.7	70.2	71.4	73.9	76.1
Standard deviation	20.4	22.7	18.9	18.1	19.8	18.5

Note: For comparison, the results of a community survey of randomly selected participants from the same community (Jelsma et al., 2004) are included.

domain and the mean values of the health states. The VAS improved from a mean of 61.7 (SD = 22.7) at baseline to 76.1 at 12 months (SD = 18.5), an improvement of 14.4%. Although the VAS score showed steady improvement, more than half of the improvement was already evident after one month (8.55%), as is depicted in Figure 2. The responses of a randomly selected community sample of 108 subjects who were within the same age range as the HIV sample are included in both of these figures for comparison. These responses were gathered in 2003 during a study on the reliability of the Xhosa version of the EQ-5D (Jelsma et al., 2004). The baseline VAS scores were not significantly correlated with the final VAS scores (rho = 0.15, $p = 0.23$), but the one-, three- and six-month scores correlated significantly (rho = 0.44, 0.70, 0.65, $p < 0.01$, respectively) with the 12-month VAS score.

Discussion

The participants of the study were all residents of an impoverished suburb of Cape Town. As in other community-based surveys (Jelsma et al., 2002), there was a preponderance of women respondents in the reference sample. This was also true of the participants and could be because approximately 14% of those on the HAART were referred from participants in the local prevention of maternal-to-child-transmission programme, which would also contribute to this bias.

The results of the study indicate that not only did the HRQoL of life of PLWHA not deteriorate during the course of the study, but that it demonstrated progressive improvement. HAART appeared to improve HRQoL through improving the health condition and in itself did not seem to result in any deterioration through toxic effects. This marked improvement in HRQoL compares very well with results from another trial, by Revicki et al. (1999), who compared triple combination therapy (SQV/ddC/ZDV) to a two-drug combination therapy (ddC/ZDV). They found that no improvement in either physical functioning or VAS score was reported, and maintenance of HRQoL was considered a successful outcome, achieved by the triple therapy but not by the other two-drug combinations. However, as they reported a higher baseline VAS score of 78 (compared to the VAS score of 62 in the current study), a ceiling effect would make maintenance of this score a valid goal of treatment for the participants in their study.

When compared to the domain and VAS responses of a community sample drawn from the same area (Jelsma et al., 2004), the 12-month VAS remained lower, although the number of problems reported in the different domains was less (Figures 1 and 2). There seemed to be a discrepancy detected between the reporting of problems with the different domains and with the more global VAS score. Despite having an equivalent or better objective health state in terms of the five descriptor domains than the community sample, the participants still reported a VAS score mean of five lower than the reference sample. The more subjective nature of the VAS is also evident in that the participants demonstrated an immediate and significant increase in VAS in response to HAART, whereas the improvement in the descriptor domains was most evident at three months. Preliminary studies indicate that adherence to the HAART regime is high (Darder et al., 2003) and this may in part be ascribed to the steady improvement in HRQoL seen over the 12 months. However, the VAS score would indicate that, after an initial rapid improvement, the participants still perceive their health status to be worse than the reference sample. This is borne out by the significant correlations between the one-month VAS score and the other scores, when compared with the baseline score. This might have implications for adherence, and the other strategies that are in place within the programme (such as continued

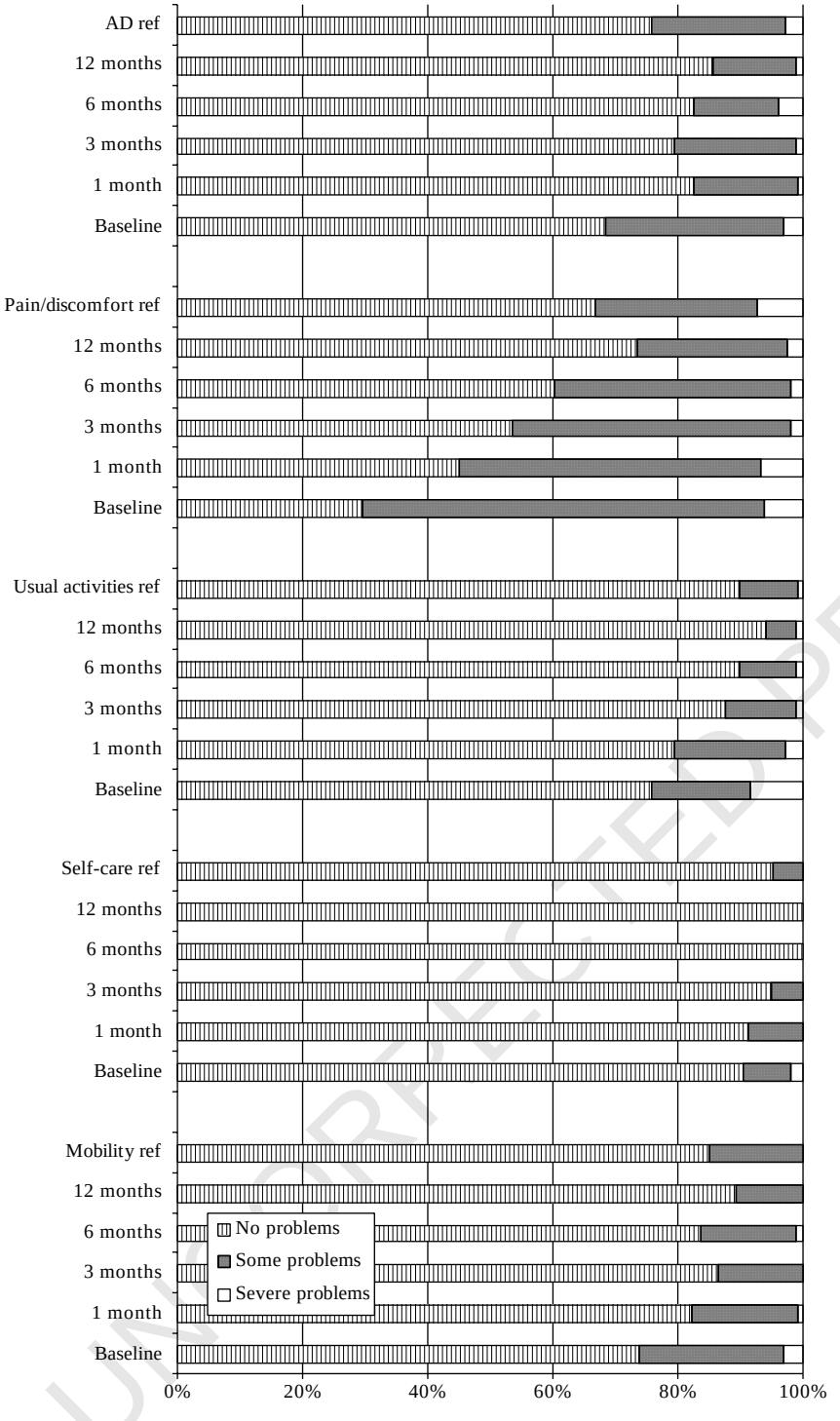

Figure 1. Reported level of problems in each of the five domains (n at baseline = 96, at one month = 102, three months = 97, six months = 98 and 12 months = 83).
For comparison the results of a community survey of randomly selected participants from the same community (Jelsma et al., 2004) are included.

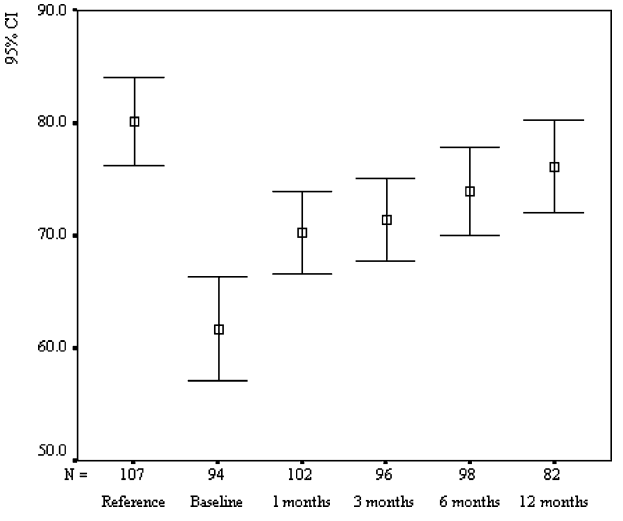

Figure 2. Mean scores and 95% Confidence Intervals of values of the Visual Analogue Scale scores. Note that some participants did not fill in the VAS. For comparison the results of a community survey of randomly selected participants from the same community (Jelsma et al., 2004) are included.

counselling and peer support groups)(Darder et al., 2003) will become ever more important to maintain the present high levels of adherence.

With the routine provision of HAART becoming a reality for PLWHA in South Africa, it is expected that the life span of a PLWHA will be considerably extended and, as Wu (2000, p. 1450) suggests, the 'most important questions will be how to maximize quality of life'. Continual monitoring of HRQoL will contribute to the evaluation of programmes and the identification of the most effective regimes of treatment with the least side effects. The EQ-5D performed well and, as suggested by other authors (Delate & Coons, 2001; Dorman et al., 1998), appeared to be a robust instrument, capable of discriminating between participants and reference group and of detecting improvement over time. However, it is important to note that although the Xhosa version of the EQ-5D has undergone validation and reliability testing in both community and disabled and hospitalized participants, it has not been validated for use in people living with HIV/AIDS specifically. For example, the omission of domains relating to vitality and sleep, which appear to be consistently compromised in PLWHA (O'Keefe & Wood, 1996; Revicki et al., 1999; Starace et al., 2002), might mean that these important aspects of HRQoL are not captured. Han et al. (2002) argue for the use of a brief and effective HRQoL instrument in HIV/AIDS research and management. The simplicity and ease of administration of the EQ-5D might make up for this failing, particularly if it is to be used routinely or, as in this study, as part of ongoing monitoring of services.

A well-designed and managed HAART programme can be very successful within a resource-constrained environment. Whereas some participants did develop side effects, the HRQoL of the majority improved progressively over the 12 months of the study. However these results were obtained with an urban group of mostly female participants and should only be generalized to the general population, particularly males and rural dwellers, with caution.

Conclusion

HRQoL is severely compromised in participants at an advanced stage of AIDS. After initiation of HAART, there is progressive improvement until at 12 months few problems are reported in any domain. However, the self-reported Visual Analogue Scale score, while significantly higher than baseline, still remains lower than the scores reported in other community samples. The toxic effects of the treatment programme would appear to be minimal, but, as the VAS score remains depressed, there may be a need for continuing support to ensure adherence after the first year of treatment.

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