Research

Self-reported health-related quality of life in persons with HIV infection: results from a multi-site interview project

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Abstract

Background: To examine demographic and behavioral associations with self-reported health-related quality of life (HRQOL) among persons with HIV infection or AIDS.

Methods: Analysis of interviews with persons ≥ 18 years of age reported through routine disease surveillance with HIV infection or AIDS to nine state and local health departments from January 1995 through December 1996. Scales were constructed from validated measures of HRQOL, and mean scores were calculated (lower scores signified poorer HRQOL). Measures of HRQOL included Overall Health, Pain, Physical Functioning, Role Functioning, Social Functioning, Mental Health, Energy/Fatigue, and Cognitive Functioning. Differences in HRQOL were examined by various demographic and behavioral factors, including taking antiretroviral medication.

Results: HRQOL data were available for 3778 persons. Factors associated with lower HRQOL scores included older age, female sex, black or Hispanic race/ethnicity, injection drug use, lower education and income, no private health insurance, and lower CD4 count. In multivariate analysis, lower CD4 count was the factor most consistently associated with lower HRQOL. Taking antiretroviral medication was not associated with differences in HRQOL regardless of CD4 count.

Conclusions: Perception of HRQOL varied in a population with HIV infection or AIDS. On most HRQOL measures, lower CD4 count was associated with lower HRQOL. Measurement of HRQOL can assist in understanding the long-term effects of disease and treatment on persons with HIV.

Background

New antiretroviral therapies introduced in the mid 1990s have allowed many persons with HIV infection to live longer before progressing to AIDS, and to have longer survival following an AIDS diagnosis [1–3]. The annual number of deaths due to AIDS in the United States peaked in 1995 and has since declined [4], resulting in an increase in the number of prevalent AIDS cases. Current clinical guidelines [5] call for persons infected with HIV to take a combination of antiretroviral medications to decrease viral load, maintain immune cell function, and prevent the development of resistant viral strains. Thus, for many pa-

tients the treatment of HIV has evolved more toward a model of chronic disease management, with patients taking a variety of potent medications for extended periods of time.

Besides clinical outcomes, health-related quality of life (HRQOL) and disability are important issues for persons treated for chronic diseases [6–11], including HIV infection [12–14]. Populations with HIV infection or AIDS have reported different levels of HRQOL, both in clinical trials [15–18] and population-based research [19–21]. We present summary information from a multi-site supplemental surveillance project that describes the levels of HRQOL reported by HIV-infected persons in different demographic and behavioral risk factor groups, stressing the relationship between disease progression and HRQOL.

Methods
Since 1990, the Centers for Disease Control and Prevention (CDC) has conducted the Supplement to HIV/AIDS Surveillance (SHAS) Project, an ongoing cross-sectional interview study designed to collect supplemental behavioral surveillance data from persons with HIV infection [22]. Persons 18 years of age or older reported with HIV or AIDS through routine case surveillance were eligible for participation. Participants were enrolled using one of three methods: (1) facility-based recruitment of all eligible persons seeking treatment at selected health care facilities in Atlanta, Connecticut, Denver, Detroit, Florida, and New Jersey; (2) population-based recruitment of all eligible persons in Arizona, Delaware, New Mexico and South Carolina; and (3) population-based recruitment of a 30% sample of men who have sex with men (MSM) and 100% of all other eligible persons in Washington State and Los Angeles County, California. During the period examined for this analysis, Arizona, Denver, Detroit, New Jersey, and South Carolina interviewed persons with HIV infection in addition to those with AIDS. (Three sites-Detroit, South Carolina, and Washington-opted not to collect data using the HRQOL module and were excluded from all analyses.) Informed consent was obtained from all participants prior to the interview, and the study has received institutional review board approval at both the CDC and local levels. Trained interviewers conducted a standardized interview in either English or Spanish that includes questions on demographic characteristics, drug and alcohol use, sexual behaviors, and medical and social service information. Data are self-reported and are not verified through medical record review or clinical tests. On average interviews take approximately 45 minutes to complete. Data were sent to CDC without any personal identifying information.

The format of the SHAS Project allows the questionnaire to be modified to collect data on additional topics of interest. From January 1995 through December 1996, a module of questions adapted from research conducted by Albert Wu and colleagues [23] was added to study the levels of self-reported HRQOL. Wu et al compiled questions from the RAND Medical Outcomes Study (MOS) [24] as well as additional items to measure other dimensions of health (energy, distress, and cognitive function) potentially relevant to HIV disease. Wu et al found that their modified health status questionnaire reliably and distinctly measured aspects of health among HIV-positive persons recruited for two clinical trials of zidovudine. HIV-infected persons who were asymptomatic had higher scores on most HRQOL dimensions-indicating relatively less disability and a better quality of life-than persons who were diagnosed with early AIDS related complex.

The SHAS Quality of Life module was used to collect information on self-reported HRQOL in the following dimensions: Overall Health, Pain, Physical Functioning, Role Functioning, Social Functioning, Mental Health, Energy/Fatigue, and Cognitive Functioning. These eight HRQOL dimensions were measured using 24 questions (a subset of the 30 MOS questions used by Wu et al). Response scores for each HRQOL dimension were transformed linearly on scale of 0 to 100. Multi-item dimensions were scored by summing item responses, and internal consistency coefficients (Cronbach's alpha [25]) were calculated. For each dimension, lower scores indicate relatively lower self-perceived quality of life for that health measure compared to higher scores.

Analysis of variance tests were used to compare crude mean HRQOL scores across demographic and behavioral categories; because the sample was large the significance level for univariate analysis was set at $P < 0.01$. Multivariate linear regression (least-squares means) was used to identify independent factors associated with HRQOL in the statistical models; analyses included variables noted from the literature as potentially associated with quality of life (e.g., age, sex, education, and income). Linear regression models were then constructed using the separate HRQOL dimension scores as the outcomes; here, the significance level was set at $P < 0.05$. Tukey-Kramer adjustments for multiple comparisons were used where appropriate. Age and education were included in the models as continuous predictor variables; CD4 count, gender, income, race/ethnicity, mode of exposure, time known to be HIV+, currently taking antiretroviral therapy (yes versus no), and type of SHAS recruitment (population-based versus facility-based) were included as categorical predictor variables. To simplify comparisons across HRQOL dimensions, we report results for models including all predictor variables, regardless of whether any indi-

Table 1: Health-related quality of life measures: definitions and the consistency of multi-item measures

Measures	Definition	Number of Items	Cronbachs's Alpha[a]
Overall Health	Perception of current health	1	–
Pain	Perception of overall pain	1	–
Physical Functioning	Extent to which health interferes with a variety of activities	6	0.84
Role Functioning	Extent to which health interferes with usual daily activities	2	0.89
Social Functioning	Extent to which health interferes with normal social activities	1	–
Mental Health	General mood or affect, including depression, anxiety, well-being	5	0.85
Energy/Fatigue	Extent to which patient felt fatigued	4	0.87
Cognitive Functioning	Extent to which reasoning or concentration was impaired	4	0.88

[a] measure of internal consistency reliability for multi-item scales

vidual variable was predictive of the outcome. All analyses were conducted using SAS Version 6.12 (SAS Institute, Inc., Cary, NC, USA).

Results

From January 1995 through December 1996, 6128 persons were identified for interview at the nine sites that administered the HRQOL module. Of these, 614 were found to have died before they could be contacted. Of the remaining 5514, 4246 (77.0%) completed SHAS interviews, 463 (8.4%) refused to participate, 394 (7.1%) could not be located, and 353 (6.4%) were located but were too ill (either physically or mentally) to participate. Sites phased out the HRQOL module at various times during the two-year period; HRQOL data were available from 3778 interviews. Persons administered the HRQOL module were demographically similar to persons who did not participate in SHAS (refused, could not be located, or too ill), except that a slightly higher percentage of those who did not participate were male (76.0% vs. 73.5%) and white (40.5% vs. 34.0%; chi-square test of proportions, P < 0.001).

The multi-item HRQOL dimensions of Physical Functioning, Role Functioning, Mental Health, Energy/Fatigue, and Cognitive Functioning were internally consistent in our sample (Table 1; all Cronbach's alpha ≥ 0.84).

Demographic characteristics of the HRQOL module participants are shown in Table 2. The median age of those providing HRQOL information was 37 years (range: 18–84). AIDS had been diagnosed in 81.1% of participants, 70.9% had known of their HIV infection for 12 months or more, and 65.0% were currently taking any antiretroviral medications (i.e., zidovudine, didanosine, zalcitabine, stavudine, or experimental HIV drugs, including protease inhibitors). The population mean score on the dimension of Overall Health was 50.4 (on a scale of 0 to 100).

Mean HRQOL scores were stratified across demographic and behavioral categories and compared by using the analysis of variance. As seen in Table 2, lower Overall Health scores were associated with older age, female sex, black or Hispanic race/ethnicity, HIV exposure through injection drug use, lower CD4 count, less than 12 years of education, no private health insurance, and lower income. Mean scores for each of the remaining HRQOL dimensions were also computed and similarly compared by demographic characteristics. In most instances in which significant differences were found, lower HRQOL was associated with the factors already listed (data not displayed).

In linear regression analyses, lower CD4 count, less education, lower income, and older age were consistently associated with lower HRQOL scores. Table 3 shows the HRQOL scores stratified by CD4 count adjusted for the other predictor variables, using the Least Squares Means technique (the group labeled "CD4 Unknown" includes those who never had a CD4 test as well as those who had a CD4 test but could not recall the result). On all but two of the HRQOL measures, self-reported HRQOL decreased as CD4 count decreased. CD4 count was not associated with the measures of Mental Health and Cognitive Function.

We were also interested in the relationship between antiretroviral therapy and HRQOL. Most of the study population (65.0%) was currently taking antiretroviral medication. Taking antiretroviral medication differed significantly by CD4 count: 75.1% of those with a CD4 count of <200 were currently taking antiretroviral medication, compared to 68.5% with a CD4 count of 200–499, and 27.3% with a CD4 count of ≥ 500 (P < 0.001, Mantel Hantzel chi-square test for trend). In univariate analysis, current antiretroviral therapy was associated with only two HRQOL dimensions: therapy was negatively associated with Role Function and positively associated with Mental Health. For the dimension of Role Function,

Table 2: Overall Health score by demographic variables (N = 3778)

Variable	Number (%)	HRQOL Measure – Overall Health score[a]	Change from reference
Age, years			
18–29	605 (16.0)	55.7 (ref.)	
30–39	1783 (47.2)	51.4[b]	-4.3
40–49	1055 (27.9)	47.2[c]	-8.5
≥50	335 (8.9)	45.4[c]	-10.3
Gender			
Male	2778 (73.5)	51.3 (ref.)	
Female	1000 (26.5)	47.7[c]	-3.6
Race/ethnicity			
White	1286 (34.0)	54.4 (ref.)	
Black	1547 (41.0)	48.5[c]	-5.9
Hispanic	901 (23.8)	47.8[c]	-6.6
Other	44 (1.2)	50.5	-3.9
Mode of exposure			
MSM	1481 (39.2)	56.3 (ref.)	
IDU	982 (26.0)	42.1[c]	-14.2
MSM/IDU	310 (8.2)	51.1	-5.2
Heterosexual contact	691 (18.3)	49.7[c]	-6.6
Other (includes NIR)	314 (8.3)	49.0[c]	-7.3
Most recent CD4 count			
<200	1950 (56.4)	46.7 (ref.)	
200–499	812 (23.5)	58.0[c]	+11.3
≥500	259 (7.5)	64.9[c]	+18.2
Unknown	433 (12.5)	48.7	+2.0
Education			
<12 years	1329 (35.2)	44.7 (ref.)	
≥ 12 years	2449 (64.8)	53.4[c]	+8.7
Health insurance status			
Private insurance	443 (12.7)	60.3 (ref.)	
Public insurance	1889 (54.0)	47.2[c]	-13.1
None	1167 (33.3)	52.3[c]	-8.0
Income			
<$10,000/year	2135 (61.1)	47.1 (ref.)	
≥$10,000/year	1357 (38.9)	57.2[c]	+10.1
Time HIV+ status known			
<12 month	1091 (29.1)	52.1 (ref.)	
≥12 months	2662 (70.9)	49.7	-2.4
Current antiretroviral therapy			
Yes	2380 (65.0)	50.8 (ref.)	
No	1279 (35.0)	50.1	-0.7
Type of recruitment			
Facility-based	2386 (63.2)	49.5 (ref.)	
Population-based	1392 (38.4)	51.8	+2.3

group totals may not sum to overall total because of missing data;
[a] analysis of variance; Tukey-Kramer adjustment for multiple comparisons;
[b] = P < 0.01; [c] = P < 0.001;
ref. = reference group; MSM = men who have sex with men; IDU = injection drug use; MSM/IDU = men who have sex with men and injection drug use; NIR = no identified risk

currently taking antiretroviral medication was associated with a lower HRQOL score (44.3) than that of persons not currently taking medication (49.8; P < 0.001). However, in the multivariate models examining HRQOL scores stratified by CD4 count, currently taking antiretroviral medication was not associated with differences in HRQOL.

Table 3: Adjusted health-related quality of life measures, stratified by CD4 count (N = 3772)

Disability Measure	CD4 <200 (n = 1950) (reference)		CD4 200–499 (n = 812)		CD4 ≥ 500 (n = 259)		CD4 Unknown (n = 751)	
	mean	95% CL	mean	95% CL	mean	95% CL	mean	95% CL
Overall Health	45.5	42.7–48.2	56.8[a]	53.7–59.9	64.7[b,c]	60.3–69.0	49.4	46.2–52.7
Pain	61.8	58.6–65.0	67.6	64.0–71.2	71.6[c]	66.6–76.6	64.8	61.0–68.5
Physical Functioning	56.6	53.4–59.7	70.7[a]	67.2–74.2	78.1[c]	73.2–83.1	67.0	63.3–70.7
Role Functioning	41.3	37.0–45.6	61.9[a]	57.0–66.7	74.9[b,c]	68.0–81.7	58.3	53.2–63.4
Social Functioning	61.8	58.7–64.9	75.3[a]	71.8–78.8	84.3[b,c]	79.4–89.1	70.5	66.9–74.2
Mental Health	57.1	54.8–59.3	59.1	56.5–61.6	61.1	57.5–64.6	58.7	56.0–61.3
Energy/Fatigue	45.4	43.0–47.7	53.3[a]	50.6–55.9	58.8[c]	55.0–62.5	49.8	47.0–52.6
Cognitive Functioning	71.0	68.6–73.4	74.2	71.5–76.9	76.4	72.7–80.2	78.0	75.2–80.8

least-squares means analysis; Tukey-Kramer adjustment for multiple comparisons; significance level P<0.05;
* includes 318 persons who never had a CD4 test
[a] significant pairwise difference: CD4 < 200 vs. CD4 200–499;
[b] significant pairwise difference: CD4 200–499 vs. CD4 ≥ 500;
[c] significant pairwise difference: CD4 < 200 vs. CD4 ≥ 500;
CL= confidence limit
factors in model: age, education, sex, race/ethnicity, HIV risk, health insurance status, income time known HIV+, current antiretroviral status, type of recruitment

Discussion

Disability and health-related quality of life are becoming increasingly important issues associated with HIV disease. New developments in the treatment of HIV have produced dramatic improvements in the clinical and immunologic health for many patients, with a resulting reduction in deaths due to AIDS in the United States. Along with clinical indicators of morbidity and mortality, measures of HRQOL (such as physical functioning, mental health, pain, and energy) can help guide treatment decisions for both patients and providers.

Like other researchers, we found that lower HRQOL scores and poorer perception of health were associated with more advanced disease. A majority of the SHAS participants had an AIDS diagnosis at the time of their interview. However, a broad range of CD4 levels is represented in the study population. Both facility-based and population-based strategies were used to recruit SHAS participants. The study population included large numbers of women, racial/ethnic minorities, and persons infected with HIV through injection drug use or heterosexual risk. These groups have not been extensively reported in previous studies of HIV and HRQOL, in which the populations have been more representative of white male clinic patients [16–18,26–28]. Where significant differences were found by univariate analysis, women, blacks, Hispanics, and persons infected with HIV through injection drug use had lower mean HRQOL scores. However, in multivariate linear regression, sex, race/ethnicity, and HIV infection risk were not associated with differences in HRQOL when stratified by CD4 count.

Several limitations should be considered in the interpretation of our findings. SHAS is a cross-sectional interview study with data self-reported by the participant. Critical indicators of disease progression, such as CD4 count, were not confirmed through clinical testing or review of medical records. Among those who reported having ever had a CD4 count, 12.5% could not recall the most recent CD4 count; on most HRQOL dimensions their scores lay between the scores for the lowest and middle CD4 groups. This finding suggests they were more advanced in their HIV disease; indeed, 83.6% were reported to the national surveillance system as having AIDS. The SHAS questionnaire also did not adequately capture the composition of a person's past and current antiretroviral therapies, or the duration of, and adherence to, those therapies. Specifically, this questionnaire does not assess the effects of protease inhibitor therapy on HRQOL, as those medications were introduced during the period the HRQOL module was used. Of the 2380 persons taking antiretroviral medications at the time of interview, only 39 (1.6%) reported taking protease inhibitors. Although other studies have also reported that questions adapted from the MOS discriminated differences in HRQOL among populations with HIV [15–19], the SHAS questionnaire's shorter 24-item subset of the MOS questions may limit direct comparison of our results with those of other studies. Still, our findings from the HRQOL analysis in SHAS generally agree with those in other published research.

Quality of life issues are also important for persons with HIV as they relate to medication adherence. Complex medication regimens and side effects can affect both quality of life and adherence [29–32]. Resistant viral strains

may emerge when adherence to antiretroviral regimens is suboptimal. After the initial HRQOL module was used, the SHAS questionnaire was modified to include questions on use of past and current medications (including protease inhibitors), duration of current therapies, measures of adherence, and reasons for lack of adherence. These questions should provide valuable new data on the relationship of disease progression, therapy, and HRQOL among participants in the SHAS Project.

Conclusions

The evolution toward treatment of HIV disease as a chronic illness presents additional challenges for patients and clinicians. Measures of health-related quality of life can provide important information to behavioral and clinical studies of antiretroviral treatment, adherence, and viral resistance – factors that ultimately influence HIV-related morbidity and mortality.

Authors' contributions

MLC developed the analysis question, conducted the data analysis, and drafted the manuscript. AKN and AJD participated in developing the analysis question, and have contributed to and approved the final manuscript.

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