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Validation of the MOS-HIV as a Measure of Health-Related Quality of Life in Persons Living with HIV and Liver Disease

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Abstract

Background—Management of HIV infection with potent antiretroviral medication has transformed HIV into a chronic condition and has shifted much of the burden of disease to co-morbid conditions such as liver disease. Liver disease (LD) alone has been shown to have a significant effect on one's health-related quality of life (HRQOL). Clinical evidence suggests that the growing number of persons living with HIV+LD may have a poorer HRQOL than persons with HIV without LD. To date, the widely accepted instrument to assess HRQOL, HIV Medical Outcomes Survey (MOS-HIV), has not been evaluated for reliability and validity in a population of HIV infected persons with LD.

Methods—HRQOL was prospectively assessed using the MOS-HIV in a sample of 532 HIV-infected adults on antiretroviral therapy (*n*=305 HIV and *n*=227 HIV+LD). In addition, participants completed standardized questionnaires of sociodemographics and co-morbid conditions.

Results—The psychometric properties of the HIV Medical Outcomes Survey were supported by testing reliability and construct, convergent, discriminative, and predictive validity. The MOS-HIV discriminated between those persons living with HIV with and without LD on the basis of the physical function subscale scores (*p*=.018).

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Conclusion—This study found the MOS-HIV valid and reliable instrument in persons with HIV +LD.

Keywords

health-related quality of life; HIV; liver disease; MOS-HIV; clinical research

Introduction

The diagnosis of human immunodeficiency virus (HIV) is now considered a chronic disease requiring complex medication regimes and often includes multiple co-morbidities that influence all aspects of an individual's well-being (Braitstein et al., 2005). Persons living with HIV may live 20 to 30 years beyond the time of diagnosis (Tedaldi et al., 2003). Treatment of HIV with highly active antiretroviral therapy (HAART) has prolonged the lives of patients; however, they are now more likely to suffer significant morbidity and mortality from liver-related disorders and their complications (anemia, end stage liver disease (LD), and hepatocellular carcinoma) than from their HIV (Cosby, Holzemer, Henry, & Portillo, 2000; Tedaldi et al., 2003). In some regions, more than 50% of persons with HIV are co-infected with chronic viral hepatitis, primarily hepatitis C virus (HCV). It is believed that the number of persons with HIV and liver disease is increasing due in part to the toxic effects of antiretrovirals on the liver and co-infection with chronic viral hepatitis (Foster, Goldin, & Thomas, 1998; Kim, 2002; Sax & Gathe, 2005). In addition to factors such as steatohepatitis, HCV viral genotype, advanced age and obesity, HIV co-infection is an important predictor of worse prognosis for patients with LD (Lawrence, 2000; Soriano, Martin-Carbonero, Maida, Garcia-Samaniego, & Nunez, 2005). Liver-related hospitalizations have increased in persons with HIV between 1996 and 2000 (Gebo, Fleishman, & Moore, 2005). Recent studies continue to demonstrate the increased risk of mortality when co-infection of HIV and HCV are present (Smit et al., 2008).

The co-morbidity of HIV and LD (HIV+LD) includes various liver conditions (acute and chronic infections, steatosis, drug toxicity and cirrhosis). The etiologies of LD in persons with HIV are approximately 85% HCV, 20% hepatitis B virus (HBV), 7% drug toxicity, and 3% other rare pathologies. Further, approximately 85% of those with acute LD progress to develop chronic LD. Long-term consequences of chronic LD include decreased health-related quality of life (HRQOL), chronic fatigue and anemia, chronic viral hepatitis, hepatocellular carcinoma, and the potential need for liver transplant. These liver conditions have been shown to have a significant effect on a person's HRQOL (Buti, Wong, Casado, & Esteban, 2006; Fleming et al., 2004; Foster et al., 1998; Hauser, Holtmann, & Grandt, 2004; Hickman et al., 2004; Ortiz, Berenguer, Rayon, Carrasco, & Berenguer, 2002; Pojoga et al., 2004; Soriano et al., 2005). However, there is no measure of HRQOL that has been validated in the HIV infected population with LD.

The HIV Medical Outcomes Survey (MOS-HIV) (Wu, 1996) is a widely used and accepted measure for HRQOL in the HIV population (Wu, Revicki, Jacobson, & Malitz, 1997). The instrument takes approximately five minutes to complete and has 35 items that assess the ten dimensions of health in individuals living with HIV (mental health, quality of life, health distress, cognitive function, energy/fatigue, overall health, role function, physical function, pain, and social function). The empirical support measuring HRQOL in the population with LD has, more often than not, been reported as overall HRQOL or is collapsed into mental and physical summary scores of the Short Form Health Survey (SF-36). Many current studies that have HRQOL as a primary outcome variable are focused on one chronic disease. For example, research has shown that adults with HIV alone, as well as those with chronic LD have impaired physical, mental, and social functioning compared to population norms. There also is a body

of literature describing the separate effects of HIV and LD on HRQOL, fatigue, and depression (Foster et al., 1998;Henderson et al., 2008;Phaladze et al., 2005;Revicki, Wu, & Murray, 1995;Sousa, Holzemer, Henry, & Slaughter, 1999;Vidrine, Amick, Gritz, & Arduino, 2005;Wilson, Hutchinson, & Holzemer, 1997). One recent study reports that HIV specific instruments need to be redesigned for patients with co-infection with HCV (Buti et al., 2006).

As the first goal of Healthy People 2010 (USDHHS, 2000) is to help individuals of all ages increase life expectancy and improve their HRQOL, the challenge for researchers and practitioners is to determine what aspects of HRQOL are affected for those with multiple co-morbid chronic diseases (Henderson, Erlen, Caruthers, & Sereika, 2006). While a recently developed instrument is now available for assessment of HRQOL in patient with HCV (HQLQv2™), it was not designed to capture issues related to co-infection with HIV. There are few systematic studies evaluating the validity of HRQOL instruments in persons with HIV +LD (Fleming et al., 2004) and there are no studies reporting on the use or validity of the MOS-HIV in this population. An instrument that assesses the complex nature of HRQOL may assist in identifying and developing specific interventions to improve the well-being of persons with HIV+LD. The purpose of this study was to examine the validity of the HIV Medical Outcomes Survey (MOS-HIV) (Wu, 1996) as a measure of HRQOL in persons with HIV+LD.

Methods

This study assessed the validity and reliability of the two-factor model of the MOS-HIV (Wu, 1996;Wu et al., 1997) using cross-sectional data obtained between 1997 and 2007 at the baseline evaluation of a parent study designed to evaluate techniques to improve medication adherence in HIV infected adults on antiretroviral therapy. This current data analysis compared baseline data from persons with HIV and persons with HIV and self-reported LD. The definition of LD was a self-reported history of liver problems or a history of significant liver disease (e.g. past or chronic viral hepatitis). Classification of the type of LD was confirmed in 95% of the LD sample first from medical record review by a trained nurse and then from self report. The precise nature of LD was not available in all cases (5 %). The baseline data were collected prior to any adherence interventions. De-identified baseline data were extracted by the data manager. Medical record review was performed within 3 months of the self-reported baseline data collection for verification of medical co-morbidities. All MOS-HIV questionnaires, medical record reviews, and sociodemographic survey measures were collected as a component of the parent study.

The inclusion criteria were HIV infected adults (18 years or older) currently on antiretroviral therapy who were required to have telephone access for the administration of the behavioral adherence intervention. Participants were excluded if they had evidence of dementia based on failure of the HIV Dementia Scale (Power, Selnes, Grim, & McArthur, 1995) screening, were living with someone else already enrolled in the study, and were blind or had motor impairment of the upper extremities, or were not presently administering their own medications. Written informed consent was obtained from all participants. The study including the cross-sectional analysis of the MOS-HIV and questionnaire data for the current report was approved by the Institutional Review Board of the University of Pittsburgh.

Measures

The MOS-HIV has been used widely in HIV related clinical trials as an outcome measure (Wu et al., 1997). The two factors or latent constructs that comprise the HRQOL are physical function and mental function. The MOS-HIV was developed from the MOS-Short Form 20 (Stewart, Hays, & Ware, 1988), with the addition of constructs that were pertinent to persons with HIV, such as energy/fatigue, cognitive functioning, health distress, and quality of life. The subscales are scored on a 0–100 scale with higher scores yielding better perceived health.

Generation of the mental and physical health summary scores, the two factors or latent constructs that comprise HRQOL, was based on an analysis of the subscale scores of over 2,500 persons with HIV in the late 1990's (Revicki et al., 1995). Subscales that loaded highly on the mental health summary score included mental health, quality of life, health distress, and cognitive function. Subscales that loaded highly on the physical health summary score included physical function, pain, and role function. The remaining three subscales (energy/fatigue, overall health, and social function) loaded on both the mental and physical summary scores (Revicki, Sorenson, & Wu, 1998).

The sociodemographic information was collected using the Sociodemographic Questionnaire, developed by the Center for Research in Chronic Diseases (CRCD) at the University of Pittsburgh. The specific self-reported data that were gathered included age (years), gender (male or female), race (collapsed into white or non-white), education (number of years), and total gross annual household income.

The Co-morbidity Conditions/Problem List is a CRCD developed survey that includes a list of medical problems as documented in the most recent medical records reviewed. The medical co-morbidities were listed and coded. The total number of medical co-morbidities was calculated.

Data Analysis

The two factor structure of the MOS-HIV with the components (mental and physical) in both groups was tested. Convergent, discriminative, and predictive validity of the MOS-HIV (Wu, 1991;1996;1997) are reported in two groups of person with HIV; those with and without LD. The relationships between selected sociodemographic factors and HRQOL in persons with HIV only and persons with HIV+LD were examined. Descriptive statistics, group comparisons, correlations, and exploratory factor analysis with oblique rotation principal components extraction were conducted using SPSS version 13.0 (SPSS, Inc., Chicago, Illinois) and EQS software package version 6.1 (Multivariate Software, Inc., Encino, California). Eigenvalues greater than 1 were retained. Convergent validity was assessed with analysis of variance. Statistical significance was pre-determined at $p<.05$ two tailed.

Results

Sample

A total of 532 individuals living with HIV (305 with HIV and 227 with HIV+LD) were included in the study. The overall sample involved merging data from an initial and continuation portion of the parent study. There were no significant differences in the samples that were merged with regard to demographics or MOS-HIV scores (Henderson, 2007, pp. 107–108). There were 35 individuals who were enrolled in both portions for which more recent data were used to assess liver disease and QOL status. There were no significant differences between the two groups with respect to gender, race, employment status, or household income. However, subjects with HIV+LD were significantly older and less educated than the HIV group without LD (See Table 1). Participants had a mean CD4 count of 455 ± 303 cell/mm^3 (range 44–1540 cell/mm^3) and 59% of the overall sample had an undetectable HIV viral load. The classifications of types of co-morbid LD are noted in Table 2. All others without evidence of LD were classified as HIV.

MOS-HIV

Although both groups had relatively poor self-reported MOS-HIV physical function, the HIV +LD group had significantly lower scores (p=.018) (M=60.6, SD±31.4) than those with HIV only (M=68.1, SD±29.1) (See Table 3). Additionally, persons with HIV+LD had significantly lower self-reported quality of life (p=.009), as measured by the MOS-HIV quality of life

subscale score (*M*=58.6, *SD*±24.4) compared to the HIV group (*M*=62.9, *SD*±24.0). Spearman's rho correlations demonstrated a moderate correlation between income and all MOS-HIV subscale scores for both groups (*r*=.300).

Exploratory factor analysis of the MOS-HIV with the 10 domain scores, excluding health transition, extracted two primary latent constructs with Eigenvalues over one. Thus, a two factor model fit the data and explained approximately 70% of the variance in persons with HIV. Role function, physical function, social function, and pain loaded on the physical health component factor or latent construct. The mental health, quality of life, health distress, cognitive function, energy/fatigue, and overall health subscales loaded on the mental health component The two factor model explained approximately 61% of the variance in persons with HIV+LD. Role function, physical function, and pain loaded on the physical health component factor. The mental health, quality of life, health distress, and cognitive function subscales loaded on the mental health component. Energy/fatigue, overall health, and social function cross loaded on both factors (See Table 4).

A two-factor confirmatory factor analysis (CFA) was performed on the 10 items of MOS-HIV using maximum likelihood estimation with robust adjustments (Satorra, & Bentler, 1994) for the HIV+LD and HIV groups. Satorra-Bentler adjustment was used to correct for non-normality of items. The first factor, mental health, had 4 simple items, while, the second factor, physical health, had 3 simple items. There were also 3 complex items that loaded on both factors. A list-wise deletion was performed for both groups.

There was a significant difference between the observed and model covariance among the items for both groups, Satorra-Bentler $\chi^2(31, N=223) = 59.252$, $p<.001$, Satorra-Bentler $\chi^2(31, N=302) = 92.278$, $p< .001$, respectively. However, since the chi-square test is sensitive to a sample size, fit indices were examined to evaluate a model fit. The fit of the two-factor CFA model in both HIV+LD and HIV groups were good: *CFI*=.991, *RMSEA*=.064, *SRMR*=.022; *CFI*=.990, *RMSEA*=.081, *SRMR*=.020, respectively (see Table 5). All factor loadings of the simple items on respective factors were significant and strong (i.e., $p< .001$ and factor loadings >.7) for both groups (see Table 4). There was very little difference between the groups in these analyses. The correlation between the mental and physical health factors were significant and very high (HIV+LD, *r*=.918; HIV, *r*=.959). This indicates that there is only one factor underlying the 10 items of MOS-HIV.

For the HIV+LD group, the overall health item did not significantly load on the mental health factor, *z*=.791, *p*=.429. The overall health item loaded highly on the physical health factor. The other 2 complex items, energy/fatigue and social function, loaded evenly on both the mental and physical health factors.

For the HIV group, the 3 complex items only significantly loaded on one factor. The energy/fatigue and overall health significantly loaded on the mental health factor. While, the social function loaded significantly on the physical health factor.

The Cronbach's alpha as a measure of internal consistency for the MOS-HIV was α=.970 for the HIV group and α=.965 in the HIV+LD group. A multi-group CFA was performed on the 10 items of MOS-HIV using maximum likelihood estimation with robust adjustments to test for factor invariance between HIV+LD and HIV groups. The combined model showed a good fit (see Baseline in Table 4). There was a significant difference on factor loadings of MOS-HIV items between the HIV and HIV+LD groups, $\Delta\chi^2(13, N=525)= 27.359$, $p=.011$. There was no significant difference between the combined model and a partial factor invariance CFA model (releasing factor loading constraints of 2 complex items), $\Delta\chi^2(9, N=525)= 11.397$, $p=.249$. The four factor loadings of the complex items, energy/fatigue and overall health, were significantly different between the two groups.

Discussion

The MOS-HIV predicted a two factor model (mental and physical) in both the HIV+LD and HIV groups. This finding supports the construct validity of the MOS SF-36 (Wu et al., 1997). Therefore, the hypothesis that the MOS-HIV predicts a two factor model (mental and physical) was supported.

Convergent validity of the MOS-HIV was supported in both groups by the loadings on the primary component of physical and mental health corresponding with the findings of other studies in HIV only samples (Wu et al., 1997). In the sample of persons with HIV without LD, the factor loading of the subscales that were expected to cross load did not do so. Conversely, the group with both HIV+LD loaded as expected based on the literature with three subscales cross loading. This study showed a potential invariance in factor loadings that were hypothesized to cross load in the HIV group, but the HIV+LD group loadings performed well. A potential rationale for the invariance is that persons now living with co-morbid HIV+LD resemble persons living with HIV in the pre-HAART era when the MOS-HIV was first developed. The loading of each subscale on the components or factors that make up the HRQOL is important to assess prior to applying summary scores as opposed to individual subscale scores of the MOS-HIV.

Discriminative validity was supported by the finding of a significant difference (p=.01) in physical function as measured by the MOS-HIV when comparing the two groups. Persons with HIV+LD demonstrated significantly lower self-perceived physical function than persons with HIV without LD. This could be due to an interaction effect of unemployment and education in this sample. Further findings of discriminative validity between the two groups showed a difference in mean scores of pain and energy/fatigue with persons with HIV+LD having more pain and fatigue with less perceived energy than persons with HIV alone. These findings may be related to potential alteration in synthetic or metabolic functioning of the liver in a diseased state.

Limitations of this study include the relatively small sample size. Additionally, the type and cause of liver disease was not always available for analysis. Specifically, this analysis did not isolate LD related to HCV, an important sub-group of HIV-infected patients and was not large enough to perform discriminate analyses between HCV and other forms of liver disease. Furthermore, individuals were screened and excluded for AIDS dementia and therefore these findings may not be generalizable to individuals with HIV+LD with more impaired cognitive function. Finally, potential bias may have been introduced as there was a lack of control for other potential co-morbidities.

In conclusion, the current study demonstrates that the MOS-HIV is a valid and reliable tool for assessing HRQOL in persons with HIV and persons with HIV+ LD. This tool encompasses the issues pertinent to the patient with HIV+LD and has been shown to be valid in this sample. Reasons for measuring HRQOL in HIV infected patients with LD include: (1) assessing differing rehabilitation needs, (2) the need for clinically meaningful endpoint in evaluating treatment outcomes, and (3) having a predictor for future treatment response (Cella, 1992). The addition of HRQOL measures has been adopted in a multitude of settings and disease processes and the ability to predict outcomes based on HRQOL is of great interest to many researchers (Vidrine et al., 2005; I. B. Wilson & Cleary, 1995). Understanding the multiple dimensions of HRQOL may assist in developing clinical interventions for patients with HIV and co-morbid liver disorders (Henderson et al., 2006). Future research is needed with more equally distributed groups matched for age and education level. The goal of the measurement of HRQOL and its domains within the population of those persons with HIV+LD would allow

identification of those areas of HRQOL that are most affected and permit the development of tailored clinical interventions aimed to improve overall quality of life.

Abbreviations

HRQOL	health-related quality of life
HIV	human immunodeficiency virus
LD	liver disease
MOS-HIV	Medical Outcomes Study-HIV Health Survey
HCV	hepatitis C virus

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Table 1

Sample demographics of persons with HIV (N=532)

Variable		Group			Statistic		
		Overall (*N*=532)	**HIV (*N*=305)**	**HIV+LD (*N*=227)**			
		***n* (%)/*M* (*SD*)**	***n* (%)/*M* (*SD*)**	***n* (%)/*M* (*SD*)**	**Chi-Sq/ *t*-test**		***p* value**
					df	**Value**	
Sex					1	1.63	.201
	Male	371 (69.7)	206 (67.5)	165 (72.7)			
	Female	161 (30.3)	99 (32.5)	62 (27.3)			
Race					1	1.79	.181
	White	261 (49.1)	142 (46.6)	119 (52.4)			
	Non-white	271 (50.9)	163 (53.4)	108 (47.6)			
Age		42.40 (7.86)	41.51 (8.29)	43.87 (7.14)	530	−3.44	.001
CD4 Count		455.94 (303.97)	492.25 (341.98)	435.43 (316.30)	Mann-Whitney	−2.01	.044
HIV Viral Load	Detectable	199 (41.1)	102 (37.5)	97 (45.8)	Pearson (1)	3.35	.067
	Undetectable	285 (58.9)	170 (62.5)	115 (54.2)			
Years of Education		13.21 (2.76)	13.35 (2.83)	12.77 (2.66)	529	2.37	.018
Total Gross Annual Household Income					5	8.08	.152
	Under 10,000	262 (49.2)	140 (45.9)	122 (52.9)			
	10,000 to 13,000	90 (16.9)	53 (17.4)	37 (16.3)			
	13,000 to 20,000	60 (11.3)	35 (11.5)	25 (11.0)			
	20,000 to 30,000	39 (7.3)	29 (9.5)	10 (4.4)			
	30,000 to 50,000	34 (6.4)	23 (7.5)	11 (4.8)			
	Over 50,0000	32 (6.0)	17 (5.6)	15 (6.6)			
	Missing	15 (2.8)	8 (2.6)	7 (3.1)			

Table 2

Classification of Co-morbid Types of Liver Disease (n=227)

HIV & Type of Liver Disease	*N*	*Percentage (%)*
HIV + Hepatitis C only	88	38.8
HIV + Hepatitis B only	32	14.1
HIV+ Hepatitis A only	15	6.6
More than one viral Hepatitis	28	12.3
HIV + Unknown Hepatitis	52	22.9
HIV + Other liver disease	12	5.3

Table 3

Comparison of MOS-HIV transformed subscales scores by independent sample *t*-test

	HIV		HIV and LD		
MOS-HIV Subscale	***n* = 306**		***n* = 227**		
	(M ± SD)	**Median**	**(M ± SD)**	**Median**	***p* value**
Overall Health	52.6±24.2	50.0	42.3±26.0	35.0	.127
Physical Function	68.4±29.1	75.0	60.6±31.4	58.3	.018
Role Function	52.1±46.3	50.0	40.2±45.7	0.0	.970
Social Function	74.1±30.0	80.0	69.0±27.0	70.0	.138
Cognitive Function	73.4±23.9	80.0	68.8±23.8	70.0	.695
Pain	65.4±27.4	66.7	55.5±27.2	55.6	.525
Mental Health	64.1±23.7	68.0	59.6±21.8	60.0	.355
Energy/Fatigue	53.2±22.6	55.0	46.8±22.8	45.0	.524
Health Distress	69.8±28.0	75.0	63.4±27.1	65.0	.794
Quality of Life	62.9±24.0	75.0	58.6±24.4	50.0	.009
Health Transition	59.7±25.4	50.0	56.7±23.4	50.0	.344

Table 4

Factor loadings from exploratory factor analysis of MOS-HIV subscores for groups.

	HIV		HIV+LD	
	Mental	**Physical**	**Mental**	**Physical**
Mental Health	.919	-	.939	-
Quality of Life	.892	-	.875	-
Health Distress	.911	-	.898	-
Cognitive Function	.912	-	.872	-
Energy/Fatigue	1.107	−.210(ns)	.529	.392
Overall Health	.675	.245(ns)	.137(ns)	.772
Role Function	-	.733	-	.712
Physical Function	-	.905	-	.907
Pain	-	.920	-	.902
Social Function	.133(ns)	.791	.490	.430
Correlation between factors	.959		.918	

All factoring loadings and correlation were significant except ones indicated.

Table 5

Multi-group CFA of MOS-HIV subscores.

Model	SB χ^2	*df*	*p*	CFI	RMSEA	SRMR	$\Delta\chi^2$	*df*	*p*
Baseline	152.504	62	<.001	.990	.075	.021			
Factor Invariance	181.959	75	<.001	.988	.074	.066	27.359	13	.011
Partial Factor Invariance	169.564	71	<.001	.989	.073	.063	11.397	9	.249