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Antiretroviral therapy adherence measurement in non-clinical settings in South India

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Optimal adherence to antiretroviral therapy (ART) is key to viral suppression, but may be impeded by psychosocial consequences of HIV-infection such as stigma and depression. Measures of adherence in India have been examined in clinic populations, but little is known about the performance of these measures outside clinical settings. We conducted a cross-sectional study of 151 Tamil-speaking people living with HIV/AIDS (PLHA) in India recruited through HIV support networks and compared single item measures from the Adult AIDS Clinical Trial Group (AACTG) scale, a visual analog scale (VAS), and a question on timing of last missed dose. Depression was measured using the Major Depression Inventory (MDI) and HIV-related stigma was measured using an adaptation of the Berger Stigma Scale. Mean age was 35.6 years (SD \pm 5.9); 55.6% were male; mean MDI score was 11.9 (SD \pm 9.1); and mean stigma score was 67.3 (SD \pm 12.0). Self-reported perfect adherence (no missed doses) was 93.3% using the AACTG item, 87.1% using last missed dose, and 83.8% using the VAS. The measures had moderate agreement with each other (kappa 0.45–0.57). Depression was associated with lower adherence irrespective of adherence measure used, and remained significantly associated in multivariable analyses adjusting for age and marital status. Stigma was not associated with adherence irrespective of the measure used. The VAS captured the greatest number of potentially non-adherent individuals and may be useful for identifying PLHA in need of adherence support. Given the consistent and strong association between poorer adherence and depression, programs that jointly address adherence and mental health for PLHA in India may be more effective than programs targeting only one.

Keywords: HIV/AIDS; depression; ART adherence; India

Introduction

Antiretroviral therapy (ART) regimens have been greatly simplified in the past decade, yet high levels of adherence are still required to reap the clinical and prevention benefits. India is home to the third largest group of people living with HIV/AIDS (PLHA; National AIDS Control Organization, 2012) and over 570,000 Indian PLHA are currently on ART (UNAIDS, 2013). Monitoring adherence is a critical part of ongoing care and requires culturally appropriate measures.

In India, adherence has been variably associated with socio-demographic characteristics (Cauldbeck et al., 2009; Rai et al., 2013; Safren et al., 2005; Sarna et al., 2008), but more consistently with psychosocial factors. Social support has been associated with higher adherence (Nyamathi et al., 2012; Shah et al., 2007), and depression is linked with poorer adherence (Anuradha et al., 2013; Nyamathi et al., 2012; Sarna et al., 2008). Although stigma has been associated with poor adherence in many settings (Kingori et al., 2012; Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007;

Rintamaki, Davis, Skripkauskas, Bennett, & Wolf, 2006; Vyankandondera et al., 2013) and noted as a barrier in qualitative studies (Joglekar et al., 2011; Kumarasamy et al., 2005), it has not been quantitatively assessed in India.

Self-report adherence measures are typically used in non-research contexts, but most have been developed in Western settings (Simoni et al., 2006). The Adult AIDS Clinical Trials Group scale (AACTG; Chesney et al., 2000) and a single-item visual analog scale (VAS; Amico et al., 2006) have both been used in India (Ekstrand, Chandu, Heylen, Steward, & Singh, 2010; Ekstrand et al., 2011; McMahan et al., 2013; Shah et al., 2007; Venkatesh et al., 2010; Walshe et al., 2010) and two studies have compared the measures with each other (Ekstrand et al., 2010; McMahan et al., 2013). However, both were conducted in private hospitals and may not be generalizable to non-clinical settings.

To assess the performance of adherence measures in a non-clinic South Indian population, we compared three single-item measures of ART adherence and evaluated

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their association with socio-demographic characteristics, HIV-related stigma, and depression. We hypothesized that poor adherence would be associated with depression and HIV-related stigma across the three measures.

Methods

PLHA were recruited into this cross-sectional study through HIV-support groups in Chennai and Vellore. Eligible participants were over 18, conversant in Tamil, and diagnosed with HIV >6 months previously. Trained, gender-matched interviewers administered questionnaires in a private location after informed consent. Participants were compensated Rs. 150/- (~US \$3.50). All procedures were approved by Institutional Review Boards at Christian Medical College, Vellore and the University of Washington.

Scales were translated into Tamil, back-translated to English to check for accuracy, and standardized to the Indian context as previously described (Jeyaseelan et al., 2013).

The AACTG single-item asked participants how many ART doses they had missed in the last four days. Those with any missed doses were considered non-adherent. In the last missed dose measure, participants were asked when they last missed a dose of each drug; those indicating “today, yesterday, earlier this week, or last week” were considered non-adherent and those indicating “1 week–1 month, >1 month, or never” were considered adherent in the past 7 days. On the VAS, participants marked an “X” on a horizontal line marked in 10% intervals from 0% to 100% to indicate the proportion of prescribed medication taken in the past 7 days. The 7-day recall period was selected to minimize recall bias and assure a comparable timeframe across measures. Measures assessed on a continuous scale were averaged if participants reported multiple drugs. We also dichotomized the AACTG and the VAS, classifying individuals who reported 100% of doses/pills taken as adherent and <100% as non-adherent in the past 7 days.

The Major Depression Inventory (MDI; Olsen, Jensen, Noerholm, Martiny, & Bech, 2003) assessed frequency of 10 depressive symptoms on a 5-point Likert scale (0 – at no time to 5 – all the time) summed for a depression score (0–50). Questions on lowered self-confidence and feelings of guilt were collapsed and symptoms categorized as present/absent to calculate a standard DSM-IV diagnosis of major depression.

The full 40-item Berger HIV Stigma Scale (Berger, Ferrans, & Lashley, 2001) was administered, but tabulated according to the 25-item version adapted to South India (Jeyaseelan et al., 2013). Overall stigma and four sub-domains (personalized stigma, negative self-image,

disclosure concerns, and public attitudes) were measured by items on a 4-point Likert scale (1 – strongly disagree to 4 – strongly agree). Scores were calculated by summing answers and reverse-scoring the single positive statement.

We calculated an intraclass correlation coefficient (ICC) to assess agreement between continuous measures and Cohen’s kappa statistic (Koopse & Weiss, 2003) for dichotomized forms. Statistical significance was assessed by Fisher’s exact tests and student’s *t*-tests in bivariate analyses; multivariable logistic regression estimated odds ratios reflecting the association of characteristics with adherence. Mediation of the stigma–adherence relationship by depression was tested using the Baron and Kenny approach (Baron & Kenny, 1986). All statistical analyses were performed using STATA MP Version 11.1 (Stata Corp, College Station, TX).

Results

Two-hundred fifty PLHA were enrolled from December 2007 to July 2008, of whom 99 were not on ART and were excluded. Fifty-six percent were male, mean age was 35.6 years (range 18–50, SD ± 5.9) and most were married or widowed (Table 1). The mean depression score was 11.9 (range 0–36, SD ± 9.1), 7.3% met the criteria for DSM-IV diagnosis of clinical depression, and the mean overall stigma score was 67.3 (range 30–95, SD ± 12.0).

Mean adherence measured by the AACTG and VAS was high (>95%; Table 2) and agreement between measures was good (ICC = 0.70). When dichotomized as non-adherent (<100%) and adherent (100%), adherence was highest by the AACTG (93.3%), followed by the last missed dose measure (87.1%), and the VAS (83.8%). Agreement between categorical measures was moderate (kappa = 0.45–0.57). The AACTG measure had the most missing data (10.6%), followed by last missed dose (8%), and the VAS (2.0%). Discrepant responses occurred in no more than 15 individuals for any two measures, with the largest discrepancy between the VAS and last missed dose measure (Table 3).

In bivariate analyses, stigma was not associated with adherence measured by the VAS ($p = 0.79$), the AACTG ($p = 0.80$), or the last missed dose ($p = 0.35$), nor were any of the stigma subdomains (data not shown). In contrast, non-adherent individuals had higher depression scores than adherent individuals (mean score VAS: 17.5 (± 9.5) vs. 10.7 (± 8.7), $p < 0.001$; AACTG: 17.9 (± 6.5) vs. 10.7 (± 8.8), $p = 0.02$; last missed dose: 17.4 (± 9.4) vs. 10.9 (± 9.0), $p = 0.005$). Younger age and single marital status were significantly associated with non-adherence by the last missed dose measure

Table 3. Comparison of individuals classified adherent and non-adherent by the AACTG, VAS, and last missed dose measures of ART drug adherence.

		Timing of last missed dose	
		≤1 week ago (non-adherent) N (%)	>1 week ago (adherent) N (%)
<i>VAS versus timing of last missed dose (n = 139)</i>			
VAS	<100% taken past 7 days (non-adherent)	13 (9.4)	10 (7.2)
	100% taken past 7 days (adherent)	5 (3.6)	111 (79.8)
AACTG			
		≥1 dose in past 4 days (non-adherent) N (%)	0 doses in past 4 days (adherent) N (%)
<i>VAS versus AACTG measure (n = 135)</i>			
VAS	<100% taken past 7 days	8 (5.9)	11 (8.2)
	100% taken past 7 days	1 (0.7)	115 (85.2)
AACTG			
		≥1 dose in past 4 days N (%)	0 doses in past 4 days N (%)
<i>Timing of last missed dose versus AACTG measure (n = 131)</i>			
Timing of last missed dose	≤1 week ago	6 (4.6)	9 (6.9)
	>1 week ago	3 (2.3)	113 (86.2)

AACTG, Adult AIDS Clinical Trials Group; VAS, Visual Analog Scale. Bolded numbers indicate discordance across measures.

Discussion

Among these South Indian PLHA, adherence ranged from 84% to 93%. The highest adherence was reported using the AACTG, the lowest with the VAS, and agreement between measures was moderate. Depression was consistently associated with lower adherence, as was single marital status (although the latter was not always statistically significant). Contrary to our hypotheses, we observed no association between stigma and adherence.

The single-item AACTG measure has been frequently used in India (Anuradha et al., 2013; Ekstrand et al., 2010;

Shah et al., 2007; Walshe et al., 2010) and correlates relatively well with viral load. Previous reports of adherence using this measure range from 74% to 97%, consistent with the 93% we observed. Although the VAS correlates with other measures in many locations (Amico et al., 2006; Oyugi et al., 2004), performance in India has been mixed. In Bangalore, high adherence measured by the VAS was associated with undetectable viral load in private hospital attendees (Ekstrand et al., 2010), but in a later assessment, adherence and viral load were only related when a composite measure including treatment

Table 4. Multivariable model of characteristics associated with adherence.

Characteristic	VAS	AACTG	Last missed dose
	AOR* (95% CI), <i>p</i> -value	AOR* (95% CI), <i>p</i> -value	AOR* (95% CI), <i>p</i> -value
<i>Depression model</i>			
Depression score [†]	0.93 (0.88–0.97), <i>p</i> = 0.002	0.93 (0.86–0.99), <i>p</i> = 0.04	0.94 (0.89–0.99), <i>p</i> = 0.02
Age (continuous)	0.97 (0.90–1.05), <i>p</i> = 0.494	1.03 (0.92–1.16), <i>p</i> = 0.57	1.11 (1.01–1.22), <i>p</i> = 0.03
Single marital status	0.37 (0.11–1.21), <i>p</i> = 1.000	0.71 (0.12–4.28), <i>p</i> = 0.71	0.39 (0.11–1.37), <i>p</i> = 0.14
<i>Stigma model</i>			
Stigma score (overall) [†]	0.99 (0.95–1.03), <i>p</i> = 0.67	0.99 (0.93–1.05), <i>p</i> = 0.78	0.97 (0.93–1.02), <i>p</i> = 0.26
Age (continuous)	1.00 (0.92–1.08), <i>p</i> = 0.93	1.04 (0.93–1.17), <i>p</i> = 0.47	1.12 (1.01–1.23), <i>p</i> = 0.02
Single marital status	0.37 (0.12–1.12), <i>p</i> = 0.08	0.62 (0.11–3.41), <i>p</i> = 0.59	0.32 (0.10–1.07), <i>p</i> = 0.07

*AOR, adjusted odds ratio; all odds ratios adjusted for all other characteristics included in the model. Missing values treated with list-wise deletion.

[†]AOR represents odds of high adherence for each point change in depression score or stigma score.

interruptions was used (Ekstrand et al., 2011). In a third study, there was no association (McMahon et al., 2013).

Older age was associated with higher adherence assessed by the last missed dose measure, similar to observations in a private Mumbai clinic using the AACTG item (Shah et al., 2007). However, most studies have found no association (Luszczynska, Sarkar, & Knoll, 2007; Safren et al., 2005; Sharma et al., 2007; Venkatesh et al., 2010; Wanchu, Kaur, Bamberg, & Singh, 2007) and the lack of consistency suggests the association may be due to chance, rather than any true relation.

Similar to other observations (Amberbir, Woldemichael, Getachew, Girma, & Deribe, 2008; Catz, Kelly, Bogart, Benetsch, & McAuliffe, 2000; Holzemer et al., 1999; Horberg et al., 2008; Steward et al., 2008; Wagner et al., 2011), depression was associated with lower adherence, irrespective of the measure used. Depression negatively impacts quality of life and engagement in care (Simoni et al., 2011), and treatment of depression can result in improved adherence (Simoni et al., 2013). In settings such as India, with a limited number of mental health professionals (Cohen, 2001), creative approaches to mental health care may include task-shifting to non-professionals, shown effective elsewhere (Simoni et al., 2013).

Given earlier observations (Kumarasamy et al., 2005; Rao et al., 2007; Rintamaki et al., 2006; Steward et al., 2008), the lack of association between stigma and adherence was surprising. The individuals in HIV-support networks studied here may have stronger social networks and better mechanisms for coping. Although we did not directly measure social support, single marital status was associated with lower adherence and married individuals, particularly in India, likely have stronger social structure and support.

Strengths of our study include assessment of multiple adherence measures in a non-clinic population and implementation of a culturally adapted stigma measure. Limitations included our lack of viral load data permitting only comparisons of the measures to each other. The time scale for the AACTG measure differed from the others, and the modest sample size may have limited statistical power.

In summary, despite modest agreement between measures, characteristics associated with adherence were generally similar. The VAS captured the greatest number of people acknowledging imperfect adherence and may effectively identify South Indian PLHA needing adherence counseling. Given the strong, consistent associations between adherence and depression, joint programs addressing both adherence and mental health should be prioritized.

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