



The Montreal Cognitive Assessment–Basic (MoCA-B) is not a reliable screening tool for cognitive decline in HIV patients receiving combination antiretroviral therapy in rural South Africa



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ABSTRACT

Background: HIV-associated neurocognitive disorders (HAND) are frequently occurring comorbidities in HIV-positive patients, diagnosed by means of a neuropsychological assessment (NPA). Due to the magnitude of the HIV-positive population in Sub-Saharan Africa, easy-to-use cognitive screening tools are essential.

Methods: This was a cross-sectional clinical trial involving 44 HIV-positive patients (on stable cART) and 73 HIV-negative controls completing an NPA, the International HIV Dementia Scale (IHDS), and a culturally appropriate cognitive screening tool, the Montreal Cognitive Assessment–Basic (MoCA-B). HAND were diagnosed by calculating Z-scores using internationally published normative data on NPA, as well as by using data from the HIV-negative group to validate the MoCA-B.

Results: One hundred and seventeen patients were included (25% male, median age 35 years, median 11 years of education). A moderate correlation was found between the MoCA-B and NPA total Z-score (Pearson's $r = 0.36$, $p = 0.02$). Area under the curve (AUC) values for MoCA-B and IHDS were 0.59 and 0.70, respectively. The prevalence of HAND in HIV-positive patients was 66% when calculating Z-scores using published normative data versus 48% when using the data from the present HIV-negative cohort.

Conclusion: The MoCA-B appeared not to be a valid screening tool for HAND in this setting. The prevalence of HAND in this setting is high, but appeared overestimated when using published norms.

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Introduction

One of the most frequent comorbidities of HIV infection is neurocognitive impairment in the form of HIV-associated neurocognitive disorders (HAND) (Habib et al., 2013; Heaton et al., 2010; Robertson et al., 2007a; Simioni et al., 2010). Timely recognition of HAND is important, as HAND can lead to loss of quality of life and everyday functioning, and virological failure due to diminished

compliance with combination antiretroviral therapy (cART) (Barclay et al., 2007; Heaton et al., 1994). A recent study showed a prevalence of 50% of any form of HAND in cART-treated HIV patients in the USA (Heaton et al., 2010). However, depending on the definitions and nomenclature used, the prevalence of HAND in developed countries of the world differs widely, ranging from 17% to 70% (Antinori et al., 2007; Su et al., 2015). This variability is even larger (between 17% and 88%) and less studied in Sub-Saharan Africa, where the majority of people living with HIV reside (Joska et al., 2011; Mupawose and Broom, 2010; Robertson et al., 2011; Singh et al., 2008).

By definition, HAND is diagnosed by applying diagnostic criteria, e.g., those of Frascati and Gisslèn, to a neuropsychological

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assessment (NPA) examining at least five cognitive domains (Antinori et al., 2007). Since this is time-consuming and requires specifically trained personnel, easy-to-use screening tests have been developed to detect neurocognitive decline. These tests are particularly needed for the mild forms of HAND, because severe forms are easily recognized in clinical practice. To date, the only cognitive screening test available intended for international settings is the International HIV Dementia Scale (IHDS) (Sacktor et al., 2005). The IHDS, although used widely and claimed to be language- and culturally neutral, has shown poor test statistics, especially in screening for milder and far more prevalent forms of HAND (López et al., 2016; Sacktor et al., 2005; Singh et al., 2008; Zipursky et al., 2013). This might be explained by the fact that the IHDS is not based on nor intended for testing and interpreting in terms of cognitive domains.

An alternative to the IHDS is the Montreal Cognitive Assessment (MoCA), which has been shown to adequately measure cognitive functioning with respect to milder forms of HAND in HIV-positive individuals in populations of developed countries (Koski et al., 2011). A more language- and culturally neutral version for administration in resource-limited settings was recently developed: the Montreal Cognitive Assessment–Basic (MoCA-B) (Robbins et al., 2013). Thus far, the MoCA-B has been compared with an NPA in two clinical trials in Asia, where it appeared to have outstanding validity (Chen et al., 2016; Julayanont et al., 2015). However, no studies have been conducted in sub-Saharan countries. This pilot study was therefore conducted to analyze the feasibility and validity of the MoCA-B compared to an NPA and the IHDS in diagnosing HAND in stable, cART-treated HIV patients in Sub-Saharan Africa.

Methods

This study took place at the research facility in Elandsdoorn, a rural township in Limpopo, South Africa, from December 2015 to March 2016. The facility is part of the Ndlovu Medical Care Group, a non-governmental organization that provides, among other things, free HIV/AIDS programs (Barth et al., 2008). This study was reviewed and approved by the local ethics committee of the University of Pretoria, South Africa.

Participants

Patients were recruited from the Ndlovu cohort study; details of the methods used in that study have been published elsewhere (Vos et al., 2017). For this sub-study, a random sample of HIV-positive and HIV-negative study participants who met the eligibility criteria were contacted by telephone and asked to participate.

HIV-positive patients were included when they had a CD4 count of at least 100 cells/mm³, a viral load of <50 copies/ml (RNA-PCR assay), and had been on stable cART for at least 6 months. HIV-negative patients needed to have been tested negative for HIV maximum 6 months prior to inclusion. All patients needed to be aged 18 years or older and be able to provide written informed consent. Exclusion criteria for both groups were the following: a previously diagnosed and documented neurological disease or neurological opportunistic infection, documented depression according to the diagnostic and statistical manual of mental disorders-IV (DSM-IV) criteria, or use of anti-depressants.

As a result of the recruitment process, this population consisted of patients who had already proved to be compliant with study visits at least once, and who mostly lived near the research facility.

Materials

The MoCA-B is a pen-and-paper cognitive screening tool examining multiple cognitive domains (e.g., executive functioning, memory, fluency, and attention). The sub-tests were chosen specifically to optimize testing in individuals with a limited level of education. For instance, it does not contain literacy-dependent tasks, and complex problem-solving tasks are designed to describe scenarios that pertain to everyday life (Julayanont et al., 2015). A subject can earn a maximum of 30 points from 10 sub-tests. A cut-off score of below 25/30 was used. The concise NPA consisted of the World Health Organization University of California–Los Angeles Auditory Verbal Learning Test (WHO UCLA AVLT) for learning and recall (Maj et al., 1993), the timed gait test (Robertson et al., 2006), the grooved pegboard test (Strauss et al., 2006), the symbol digit modalities test (SDMT) (Strauss et al., 2006), the color trail test (CTT) (D'Elia et al., 1996), and the digit span test (Strauss et al., 2006) (see Table 1).

Although the original forms were used, the patient's own language was used for the instructions and, if applicable, the content of the neuropsychological tests. For instance, the words used in the fluency tasks were given in the participants' native language. A standardized administration manual in English was translated (forward and backward) into isiZulu and Northern Sotho by a certified translation company. At the start of the assessment, the participant chose his or her most fluent language as the preferred language of administration: English, isiZulu, or Northern Sotho.

Data collection

Detailed information on sex, age, paid work, mental health, smoking and alcohol habits, cART, concomitant medication, and laboratory values (CD4, viral load) were collected from the Ndlovu

Table 1
Tested neuropsychological assessment sub-tests and explanations

Test	Domain	Explanation: patient is asked to . . .
Timed gait	(Gross) motor function	Walk a predetermined distance as fast as possible
Grooved pegboard	(Fine) motor function	Place pegs in a pegboard as fast as possible
Digit symbol modalities	Information processing	Match digits with their corresponding symbols as fast as possible
Color trails 1	Information processing	Connect numbers in ascending order as fast as possible
Color trails 2	Information processing/executive functioning	Connect numbers in ascending order when alternating between two colors
Color trails ratio	Color trails 2/color trails 1	Ratio between the two color trails
Digit span – forwards	Attention	Repeat an increasing span of numbers forwards
Digit span – backwards	Executive functioning	Repeat an increasing span of numbers backwards
WHO UCLA AVLT	Verbal memory	Remember a list of 15 words after 5 repetitions: A1–A5 is the sum of all words remembered after 5 repetitions; A7 is the number of words remembered after 30 min

WHO UCLA AVLT, World Health Organization University of California–Los Angeles Auditory Verbal Learning Test.

cohort study. For the cognition sub-study, the IHDS, the MoCA-B, and a concise NPA were added. All tests and questionnaires were administered by a trained local counselor using standard procedures described in the accompanying manuals and/or from published instructions (Robertson et al., 2006; Sacktor et al., 2005; Strauss et al., 2006). The MoCA-B was conducted using the standard instructions on the MoCA website (<http://www.mocatest.org>).

Statistical analysis

Shapiro–Wilk tests were used to test for normality. The Mann–Whitney *U*-test or Chi-square test was performed to analyze group differences in demographic characteristics. Pearson's correlation coefficient was used to assess correlation.

Raw NPA test scores were transformed into age/education-adjusted *Z*-scores using (1) published normative data from comparable sub-Saharan populations (Robertson et al., 2007b, 2006; Singh et al., 2010), and (2) data from the present study HIV-negative population. *Z*-scores were calculated by subtracting the mean of either norm group from an individual's raw score, and dividing the result by the standard deviation (SD) of the normative data. Because of a significant difference in age between the HIV-positive and HIV-negative subjects, the mean and standard deviation of the HIV-negative group were adjusted using a regression coefficient for age. These *Z*-scores were summed and averaged to create a composite *Z*-score. The timed gait, CTT, and grooved pegboard scores were multiplied by -1 , because for these tests a higher score means a worse performance.

The criteria of Frascati and Gisslèn were used to diagnose HAND (Antinori et al., 2007; Gisslèn et al., 2011). According to the Frascati criteria, a person has severe HAND (HIV dementia) when he or she scores at least two SD below the mean on at least one sub-test in at least two domains. The qualification for mild HAND is met when at least one SD below the mean is scored on at least one test in at least two domains. Information on interference with daily functioning is needed to differentiate between asymptomatic neurocognitive impairment and mild neurocognitive disorder. For the Gisslèn criteria, an average domain score of 1.5 SD below the mean on at least two domains is used to define mild HAND, and two SD below the mean is used to define severe HAND.

As NPA is the gold standard for diagnosing HAND, the feasibility and validity of the MoCA-B was measured by performing a receiver operating characteristics (ROC) curve analysis and calculating the area under the curve (AUC) values. In this ROC analysis, the test

variable, i.e. the MoCA-B with a cut-off score of below 25, is compared to a state variable, i.e. HAND or no HAND.

Furthermore, the total and domain scores were compared to the results of the NPA. The MoCA-B evaluates three cognitive domains that were also evaluated in the NPA, namely executive functioning, attention, and memory. All statistical tests and procedures were conducted using IBM SPSS Statistics version 21 (IBM Corp., Armonk, NY, USA).

Results

Participants

At the start of the present study, 1173 participants (ratio of HIV-positive to HIV-negative 1:2) had been enrolled in the Ndlovu cohort study, which started recruiting in November 2014. One hundred and seventeen participants (10%) were included in this sub-study, of whom 44 were HIV-positive and 73 were HIV-negative. All participants had visited the research facility for the Ndlovu cohort study at least once already, and 10 in the HIV-positive group (23%) and 20 in the HIV-negative group (26%) had visited the site twice before. The main reason for non-participation of eligible participants was logistical; they lived too far away from the research site.

Participants were predominantly female (76%), and there was a high rate of unemployment (84%) (Table 2). HIV-positive patients were older than HIV-negative controls (40.5 years versus 32.4 years; $p < 0.05$) with no difference in years of education, which averaged 11 years. There was a significant difference in native language, with more isiZulu speakers in the HIV-positive group and more Northern Sotho speakers in the HIV-negative group ($p = 0.04$). HIV-positive participants had a mean CD4 count of 530 cells/mm³.

Feasibility of the MoCA-B

Administration of the MoCA-B was feasible in all participants, with a mean administration time of 13.6 (SD 3.3) min. The mean score on the MoCA-B was 22.1/30 for the HIV-positive group and 24.2/30 for the HIV-negative group ($p < 0.05$). The MoCA-B total score was compared with the NPA composite *Z*-scores. Based on published normative data for the NPA, a moderate correlation (Pearson's $r = 0.36$, $p = 0.02$) was found. This was comparable to the correlation between the IHDS and NPA total *Z*-score (Pearson's $r = 0.44$, $p < 0.01$). Moreover, when evaluating the three specific

Table 2
Baseline characteristics

	Total	HIV-positive	HIV-negative	<i>p</i> -Value
Number	117	44	73	
Male (%)	24.6	18.6	28.2	0.25
Age, median years (IQR)	35 (15)	41 (13)	29 (15)	<0.01
Education, median years (IQR)	11 (3)	11 (3)	11 (3)	0.95
Illiterate (%)	4.4	7.0	2.8	0.35
Unemployed (%)	83.8	88.6	80.8	0.43
Smoking habit (%)	19	20	18	0.91
Alcohol consumption (%)	32	25	37	0.26
Language, % isiZulu/Northern Sotho	50.4/44.4	63.6/29.5	42.5/53.4	0.04
Mean CD4 count/mm ³ (SD)	–	530 (232.1)	–	NA
Suppressed viral load (%)	–	100	–	NA
Mean months since diagnosis (SD)	–	85.12 (55.9)	–	NA
Mean months on cART (SD)	–	70.33 (53.9)	–	NA
On EFV (%)	–	93	–	NA
Depressive symptoms (PHQ-9 > 10)	–	11%	6%	0.29

cART, combination antiretroviral therapy; EFV, efavirenz; IQR, interquartile range; NA.; PHQ-9, Patient Health Questionnaire; SD, standard deviation. NA: not applicable.

cognitive domains, there was only a moderate correlation for the memory sub-tests ($r=0.44$, $p=0.03$) and no significant correlation between attention ($r=-0.09$, $p=0.58$) or executive functioning ($r=0.25$, $p=0.10$) sub-tests of the MoCA-B and the NPA.

The ROC curves for the MoCA-B and the IHDS screening for HAND diagnosed with the Frascati criteria are depicted in [Figure 1](#). The AUC was 0.59 for the MoCA-B and 0.70 for the IHDS. When norms from the HIV-negative group were used for the NPA composite Z-scores, these results also showed only a moderate correlation with the MoCA-B scores (Pearson's $r=0.58$, $p<0.01$). Test characteristics of the MoCA-B according to the different forms of HAND (mild/severe) and results of the NPA sub-tests are provided in the [Supplementary Material](#).

Prevalence of HAND according to the diagnostic criteria used

Using the Frascati criteria, the overall prevalence of HAND was 66%, while the prevalence of mild forms of HAND was 54%, based on the published norms. However, when using the HIV-negative group as reference, the overall prevalence of HAND declined to 48% and the prevalence of mild forms of HAND to 43%. A comparable pattern was seen for the Gisslèn criteria, namely 14% versus 9% for published norms and 7% versus 5% for comparable HIV-negative norms.

Discussion

The validity of cognitive screening tools to detect HAND and mild forms of HAND in a Sub-Saharan African population was investigated. The MoCA-B appeared not to be a valid screening tool for HAND in this cohort in South Africa. Additionally, the prevalence of HAND in this setting was, as expected, high, but could have been overestimated using currently available published norms.

Because of the difficulties associated with conducting a full NPA, valid and easy-to-use cognitive screening tests are much needed in resource-limited settings. However, insufficiently tested screening tools with poor validity should be avoided to prevent over- or under-diagnosing of the problem. The supply of language- and culturally appropriate cognitive screening tests is limited; only the IHDS is currently available. This study evaluated the validity of the MoCA-B. The finding that the MoCA-B has poor validity is not consistent with previously published reports on this test ([Chen et al., 2016](#); [Julayanont et al., 2015](#)). However, as mentioned before, the only two studies performed previously with the MoCA-B were conducted in Asia and not with HIV patients.

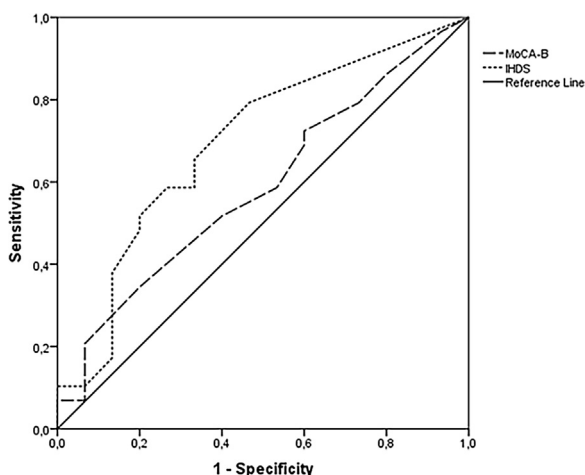


Figure 1. ROC-curve for the MoCA-B and IHDS diagnosing any form of HAND.

The MoCA-B demonstrated the best test characteristics when screening for severe forms of HAND. However, easy and short diagnostics are more urgently needed for the mild forms of HAND, which are not readily detected in regular clinical consultations. The correlation between MoCA-B and the NPA total Z-score was only moderate. This might be explained by the fact that the MoCA-B does not include speed of information processing, which was found to be the most affected domain in the NPA in this study population. Therefore, a future screening tool incorporating speed of processing might be more appropriate.

Furthermore, both HIV-positive and HIV-negative participants from the same cohort were examined in order to have a highly comparable control group. The prevalence of HAND was at least 25% lower when using these normative data, as opposed to previously published normative data obtained from other sub-Saharan countries. This stresses the importance of collecting suitable normative data for different cultural groups in sub-Saharan settings, because overestimation otherwise occurs. Therefore, caution is required when interpreting results obtained with ill-fitting normative data.

This study had a few limitations. Due to the nature of this pilot study, the sample size was relatively limited. The inclusion of mostly unemployed patients may have caused bias in the reported prevalence of HAND. On the other hand, this probably represents the subgroup of patients most affected by HAND in everyday life and also the target population for investigating diagnostic options. Moreover, as a result of the recruitment process, this sample comprised patients who had already shown compliance with study visits. This may have caused the study population to represent a more compliant, better-functioning group. However, if this affected the HAND incidence rates, they would most likely be lower than the actual rates, meaning that the incidence of HAND in the overall population would be even higher.

In conclusion, by using an appropriate NPA, and more importantly, fitting normative data in the form of HIV-negative individuals in the same socio-economic region, this study clearly showed that the easy-to-use MoCA-B was not reliable in screening for HAND. In addition, using a control group of HIV-negative individuals is of great importance when studying HAND in resource-limited settings.

Conflict of interest

None. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.ijid.2017.11.024>.

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