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SOETOMO SCORE AS A PREDICTOR OF HIV-ASSOCIATED NEUROCOGNITIVE DISORDERS

Running head: Soetomo Score and HIV-Associated Neurocognitive Disorders

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ABSTRACT---Background *HIV-Associated Neurocognitive Disorders (HAND)wasone of theneurological complicationsof HIVinfection. However, there were no biomarkers have been sufficiently validated for prognosis HAND.*

Objective: *To develop a scoring system and determine prognostic values of Soetomo Score as Predictor of HIV-Associated Neurocognitive Disorders (SSP HAND).*

Methods: *The case-control study was performed at the UPIPI out-patient clinic. The examination is performed using MoCa-Ina.Eight parameters which were possible to be a predictor of HAND were analyzed by bivariate and multivariate. Results were analyzed using calibration test and discrimination test produced Area Under Curve (AUC) value. The cut-off point could make identification of good and bad prognostics.*

Results: *The equation of SSP HAND was Y=-4.164+1.249 score total of SSP HAND. AUC value of this score was 80.9% (95% CI=71.1%-90.6%). The value of SSP HAND was ≥3.5,it means that the sensitivity was74,4% and the specificity was79.5%. Subject with score 0–3 had good prognostic while score 4–5 had bad prognostic.*

Conclusion: *Value of SSP HAND ≥3.5 could make a good prediction of HAND.*

Keywords---*Soetomo score, Neurocognitive disorder, Prognostic test*

I. INTRODUCTION

Human Immunodeficiency Virus (HIV) infection has become an epidemic worldwide including in Indonesia. The Ministry of Health of the Republic of Indonesia reported the number of HIV and Acquired Immunodeficiency Syndrome (AIDS) cases cumulatively in 33 provinces and 300 districts/cities in Indonesia until September 2014 was 150,296 and 55,799 cases respectively. Incident of HIV and AIDS was 22,869 and 1,876 AIDS cases. The cumulative number of national AIDS cases is 16.59 per 100,000 population and East Java ranks second after DKI Jakarta (1,2).

The discovery of antiretroviral drugs (ARVs) in 1996 led to a revolution in the treatment of people living with HIV and AIDS. Although it has not been able to cure the disease, ARV therapy dramatically reduces mortality, morbidity, and improves the quality of life of people living with HIV. On the other hand, the number of HIV-Associated Neurocognitive Disorders (HAND) increased sharply. It is estimated that the HAND prevalence is 40-70% (3-

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6)among HIV patients. There are three reasons why HAND has been the subject of discussion in the past decade. First, HIV becomes a chronic disease with a physical condition that almost approached a normal person. Second, there is an increase in life expectancy in HIV patients so that it can survive to older age. Third, although ARV therapy is very effective in reducing viral replication and restoring immune function, HAND is still high prevalence (3-6).

To our knowledge, there is no biomarker for the prognosis of HAND incidence.Therefore, scoring model is needed to predict cognitive impairment in HIV patients.There have been several prognostic scores that calculate the incidence of dementia in general. Such scores are common with reference to the incidence of cognitive impairment alone (7,8).But there is no cognitive impairment score on HAND that involves specific predictors of HIV infection such as duration of ART, the number of CD4 lymphocyte, and CNS opportunistic infections. This specific scoring model has been successfully established in diabetes mellitus by taking into account the specific predictors of diabetes mellitus (7-9).

This study aimed to develop a scoring model with good prognostic value in predicting cognitive impairment in HIV, called as the Soetomo Score for a Predictor of Cognitive Disorder in HIV Infection (SSP GKH).It consists of predictor parameters of cognitive impairment in HIV patients including age, education level, duration of ART, gender, CD4T lymphocytes, vascular risk factors, CNS opportunistic infections, and body mass index (BMI).

The predictor parameters of cognitive impairment in SSP GKH are obtained from all subjects of HIV patients to be analyzed according to prognostic studies with categorical outcomes. The analysis consists of descriptive analysis, bivariate statistics, multivariate statistics, model selection and scoring system (10).

II. METHODS

Design and Location Research

Case control was used as design of this study. The design examines the relationship between exposure and disease by comparing the case group and control group based on their exposure status. The study population was all HIV patients receiving ART in HIV polyclinic of Dr.Soetomo General Hospital. Affordable populations are all HIV patients receiving antiretroviral therapy in HIV polyclinic of Dr.Soetomo General Hospitalfrom September 2015 to December 2015who fulfilled the criteria of inclusion and exclusion.

Population Research

The inclusion criteria in this study were HIV positive patients who were diagnosed by performing a 3-method test; MOCA-Ina examination results show abnormalities; currently on ART treatment, patients aged 17 and older; and patients who are cooperative and willing to be included in the study by signing an informed consent.Exclusion criteria were HIV patients with GCS less than 456 and patients who can not read and write.

Chi-square test is used for bivariate statistical analysis on all variables with categorical measurement scale anddetermine odds ratio. We performed logistic regression with backward stepwise method. The determination of the cut-off point to make predictions of cognitive impairment in HIV patients will be done from all CNS GKH values obtained from all subject patients.

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III. RESULTS

The process of data collection of research subjects was conducted from November to December 2015. In all subjects, demographic and clinical data were recorded. All subjects underwent examination of MoCA-Ina at UPIPI outpatent clinic of Dr. Soetomo General Hospital Surabaya.

Total of 78 subjects was divided into 39 normal subjects with normal MoCA-Ina examination results that called as control group and 39 subjects with abnormal MoCA-Ina examination results hereinafter referred to as case group.

Demographic Data

Demographic data of study subjects covering age, sex and education can be seen in table 1.We found 19 men (42.2%) in the case group less than the control group of 26 men (57.8%). There was a difference of sex proportions between each group, but this difference was not statistically significant with p=0.109 (table 1).We obtained 14 people aged 40 years and over (35.9%) in the case group higher than the control group of 12 people aged over 40 years (30.8%). There was a difference in the proportion of age between each group, but this difference was not statistically significant with p = 0.631 (table 1).

In the case group, it was found that 37 people had received 12 years compulsory education (94.9%), more than the control group consisting of 29 people had received 12 years compulsory education (74.4%). There was a difference in the proportion of educational levels between each group and this difference was statistically significant with p=0.012 (table 1).

Clinical Data

From the data collected, there were clinical data including BMI, number of T-cell lymphocytes at nadir, duration of ART therapy, CNS opportunistic infections, history of vascular risk to be predictors of SSP GKH. BDI scores are also done to rule out major depressive disorders. Clinical data of research subjects can be seen in table 2.

SSP GKH Parameters

Eight candidate of SSP GKH parameters include: age, sex, education level, duration of ART, CD4 T lymphocyte count, vascular risk factors, CNS opportunistic infections, and body mass index (BMI).Bivariate analysis was done by Chi-square test. Crosstab performed between eight candidates of SSP GKH variable with MOCA-Ina score. The analysis resulted an Odds Ratio with 95% CI and a p value of each parameter. Variables with OR>1 and p value <0.25 in bivariate analysis will be tested using multivariate analysis (Table 3).

Six of the eight candidate SSP GKH variables were predictors of cognitive impairment, namely: gender (OR=2.11, 95% CI=0.84-5.26), education level (OR=6.38, 95% CI=1.29-31.41), duration of ART (OR=3.053, 95% CI=1.16-7.93), number of CD4 lymphocyte (OR=4,138; 95% CI=1.041-16.44), and opportunistic infections of CNS (OR=6,38; 95% CI=1.29-31.41) (table 3). The six parameters were further analyzed by multivariate analysis.

Logistic regression analysis was used in multivariate analysis with dependent variable of categorical dichotomes in case control research. Logistic regression method used is backward stepwise method. (Table 4).

The results showed that only four parameters were statistically significant (p <0.05) as a predictor of cognitive impairment in HIV, ie: educational level, CD4 T lymphocytes, CNS opportunistic infections, and duration of antiretroviral therapy. These four parameters will become the prognostic model of SSP GKH.

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Accuracy of Prognostic Models

The accuracy of the prognostic model depends on the value of calibration and discrimination. In the prognostic model with categorical form output, calibration values were tested by Hosmer and Lemeshow test while discriminatory values were tested with Area Under the Curver (AUC)(10).The value of discrimination is tested with the Receiver Operating Characteristic (ROC) procedure. From this procedure, we get the value of Area Under Curve (AUC) SSP GKH of 80.9% (95% CI = 71.1% - 90.6%) (Figure 2).

The ROC procedure also produces some alternative cutoff points from the GKH SSP along with their sensitivity values then followed by the calculation of specificity values. Table 6 shows the sensitivity and specificity values at some of the points of intersection. The optimal cutoff point obtained from the intersection of the sensitivity curve and the specificity curve. The point obtainedwas≥3.5 (figure 3) with sensitivity of 74.4% and a specificity of 79.5% (table 5).The closest number which is greater than 3.5 is 4. It means thatthe subject has a poor prognosis if the subject score is at least 4.

Scoring System

The step to produce the scoring system are scoring for each variable, transforming the data according to the score, making the total score variable, making the scoring model, calculating the probability of the subject having cognitive impairment, and making the scoring card (10).

From the analysis, we got the equation: Y = -4,164 + 1,249 of total SSP GKH score (95% CI=1,856-6,542). The probability of a subject with cognitive impairment can be seen in Table 6. From these results we can create a scorecard named SSP GKH (table 7).

IV. DISCUSSION

This study is a prognostic study to determine predictors of cognitive impairment in HIV patients. The research design used is case control because it is considered in accordance with the purpose of the researcher. Consecutive sampling technique is used because this technique is the best and easiest nonprobability sampling (11).

The sample size is determined by the formula of the sample for prognostic research with the output of the categorical form of the dichotomes. The value of the proportion of securities in the control group was determined based on preliminary research. The minimum sample size required is 32 people per group based on the calculations performed. The subjects obtained are allocated into two groups; first group with normal MOCA-Ina results called controls, and second group with abnormal MOCA-Ina are referred to as cases. The case and control groups in this study each had 39 subjects.

Statistical analysis was performed using SPSS 22.0 program. Bivariate analysis was done by Chi-square test. Parameters with OR> 1 and p values <0.25 in bivariate analysis will be analyzed using multivariate (backward stepwise method). Parameters with significant multivariate test results will be defined as GKH SSP parameters. Furthermore, these parameters become the prognostic model of GSP SSP whose accuracy depends on calibration and discrimination values. The calibration values were tested by Hosmer and Lemeshow test while discrimination values were tested with Area Under the Curver (AUC). The best model produced will be a scoring system which can be used in daily applications (10,12).

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The study obtained gender characteristics (Table 1) out of a total of 78 samples, 58% percent of men and 42% of women. A multinational-based study (SMART) of 292 samples obtained more men by 48.2% and females by 41.8% (13).A HAND study in Singapore received 132 samples with 84.3% of men and women of 15.7% (14).

Characteristics of research subjects based on educational level were obtained from a total of 78 samples; 85% percent for> 12 years and 15% for <12 years. Studies on HIV infection have shown that individuals with more than 12 years of education have better executive functioning skills than people with <12 years of education(15,14).

Two independent variables, namely age and BMI, were not among the predictors of cognitive impairment in this study. BMI has been excluded from predictors at bivariate analysis and age as well. While the vascular risk factor was excluded when the first step of logistic regression analysis was backward stepwise method. In the second step, sex came out of the analysis.

The duration of antiretroviral therapy was a predictor of cognitive impairment in this study. Some literature suggests that duration of antiretroviral administration is a factor in the prognosis of cognitive impairment (16-18).One study found that clinically significant cognitive improvement improvements peaked around 24-36 weeks after combination ART and continued until a year later.

The nadir T lymphocyte was a predictor of cognitive impairment. This is consistent with the literature that suggests when immune suppressed on the inner level, as reflected in nadir CD4. This causes permanently damaged neuronal cells that contribute to HAND(19,20).

CNS opportunistic infections predict the occurrence of cognitive impairment in this study. HIV infection itself can cause neuropathological changes, CNS opportunistic infections among HIV patients often result in more severe damage than brain structures (21).

Four predictors of this cognitive impairment become parameters of SSP GKH model. After a logistic regression analysis was performed on four GKH SSP parameters (duration of antiretroviral treatment, CNS opportunistic infections, CD4 T lymphocytes, and level of education). From the ROC procedure, SSP GKH has AUC of 80.9% (95% CI = 71.1% - 90.6%). AUC value of 80.9% statistically shows that the SSP GKH model has strong prognostic value.

We found an optimal cut-off point of 3.5 which is also a statistical point of intersection (table 5 and figure 3). This point was derived from the intersection of the sensitivity curve and the specificity curve (Figure 3). At a value of 3.5 SSP GKH has a sensitivity of 74.4% and a specificity of 79.5% (table 5).

V. CONCLUSION

This study produces the SSP GKH model which has the following equation: SSP GKH=-4.164+1.249 Total Score of SSP GKH. This equation successfully developed into a scorecard that is easily applied in the field. The SSP GKH value of≥3.5 indicates a poor prognosis in cognitive disorders. The SSP GKH value of <3.5 indicates a good prognosis with sensitivity of 74.4% and a specificity of 79.5%.

The advantages and disadvantages of SSP GKH as a predictor of cognitive impairment in HIV infection is necessary to be studied further by testing external validation. In addition, further research is needed to include simple laboratory, radiological or other comorbid examinations.

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TABLES

Table1:Characteristics of Subjects

	MOCA-Ina				*p*	OR (95% CI)
	Case		Control			
	N	%	N	%		
Sex						
Woman	20	60,6	13	39,4	0,10	2,11
Man	19	42,2	26	57,8	9	(0.84 -5.26)
Age						
≥40 years	14	35,9	12	30,8	0,631	1,26
<40 years	25	64,1	27	69,2		(0,49 -3,237)
Level of Education						
≤12 years	37	94,9	29	74,4	0,01	6,38
>12 years	2	5,1	10	25,6	2	(1,29 -31.41)

Table2:Characteristics of Subjects Based on Clinical Data

Variables	**Case Group** (n=39)	**Control Group** (n=39)	**Total** (n=78)	**p Value**
ART Duration				
≤1 years	27 (58,7%)	19 (41,3%)	46	0,020
>1 years	12 (37,5%)	20 (62,5%)	32	
Number ofCD4				
≤200 cell/mm^3	35 (54,7%)	29 (45,3%)	64	0,033
>200 cell/ mm^3	4 (28,6%)	10 (71,4%)	14	
Vascular risk factors				
Yes	16 (64,0%)	9 (36,0%)	25	0,089
No	23 (43,4%)	30 (56,6%)	53	
CNS opportunistic infections				
Yes	6 (75,0%)	2 (25,0%)	8	0,120
No	33 (47,1%)	37 (52,9%)	70	
Body Mass Index (BMI)				
Abnormal	10 (55,6%)	8 (25,0%)	18	0,591
Normal	29 (48,3%)	31 (51,7%)	60	
BDI	12,35± 10,29	7,76± 8,33		0,034

Table3: Odds Ratio Value and 95% CI Candidate of SSP GKH Parameters

No.	Variabels	Odds Ratio (95 % CI)	p Value
1.	Level of Education	6,38 (1,29 -31.41)	0.012
2.	ART Duration	3,05 (1,16-7,93)	0.020
3.	Age	1,26 (0,49- 3,24)	0.631
4.	Sex	2,11 (0.84-5.26)	0.109
5.	T CD4 lymphocytes	4,14 (1,04-16,44)	0.033
6.	Vascular risk factors	2,32 (0,87 - 6,18)	0.089
7.	CNS opportunistic infections	6,38 (1,29 -31,40)	0.012
8.	Body Mass Index (BMI)	1,34 (0,46 - 3,85)	0.591

Table4:Logistic Regression Analysis WITH Backward Stepwise Method

		B	S.E.	Wald	df	Sig.	Exp( )
Step 1[a]	Education(1)	1,933	,879	4,831	1	,028	6,909
	CD4(1)	1,563	,854	3,352	1	,067	4,775
	OPPCNS(1)	2,164	1,075	4,050	1	,044	8,708
	ARTDuration (1)	1,238	,555	4,979	1	,026	3,450
	Vasculer(1)	,112	,652	,030	1	,863	1,119
	Sex(1)	,729	,570	1,636	1	,201	2,074
	Constant	-4,356	1,270	11,770	1	,001	,013
Step 2[a]	Education(1)	1,957	,869	5,075	1	,024	7,076
	CD4(1)	1,600	,828	3,737	1	,053	4,954
	OPPCNS(1)	2,228	1,015	4,817	1	,028	9,280
	ARTDuration (1)	1,237	,555	4,969	1	,026	3,447
	Sex(1)	,708	,556	1,622	1	,203	2,030

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	Constant	-4,372	1,268	11,891	1	,001	,013
Step 3[a]	Education(1)	2,042	,860	5,634	1	,018	7,709
	CD4(1)	1,674	,814	4,229	1	,040	5,334
	OPPCNS(1)	2,047	,962	4,527	1	,033	7,743
	ARTDuration (1)	1,158	,540	4,590	1	,032	3,183
	Constant	-4,143	1,213	11,674	1	,001	,016

Table5:The Value of Sensitivity and Specificity of Soetomo Score From Some Alternative Cut Points

No.	Positive if Greater Than or Equal To[a]	Sensitivity	Specificity
1	0,0	1,000	0,000
2	1,5	1,000	0,128
3	2,5	0,897	0,333
4	3,5	0,744	0,795
5	4,5	0,154	0,974
6	6,0	0,000	1,000

Table6:Total Score of SSP GKH

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	SSPGKH	1,249	,321	15,115	1	,000	3,486	1,857	6,542
	Constant	-4,164	1,119	13,844	1	,000	,016		

Table7:The Probability of a Subject To Have a Cognitive Impairment on Each Score

Patient Score	Constants	Coefficient	SSP GKH equation	Probability (%)
0	-4,164	1,249	-4,164	1,53

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1	-4,164	1,249	-2,915	5,14
2	-4,164	1,249	-1,666	15,89
3	-4,164	1,249	-0,417	39,72
4	-4,164	1,249	0,832	69,67
5	-4,164	1,249	2,081	88,9

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