Preliminary Report

Prevalence of Adrenal Insufficiency in Critically Ill Patients with AIDS

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Background: *The most common endocrine disorder in patients with human immunodeficiency virus (HIV) is adrenocortical dysfunction. The prevalence of adrenal insufficiency in patients with AIDS is unclear, partly due to different tests, doses of adrenocorticotrophic hormone (ACTH), and criteria used. In addition, there is controversy regarding the assessment of adrenal insufficiency in patients with and without critical illness.*
Objective: *To help clarify the prevalence of adrenal insufficiency in patients with AIDS both in critical and non-critical illness, the authors compared the prevalence based on the high-dose ACTH stimulation test.*
Material and Method: *There were 26 patients with AIDS (19 males and 7 females) with a mean age of 33.6 years (range: 22-46 years). Twelve and 14 patients were in critical and non-critical illness, respectively.*
Result: *Overall, the prevalence of adrenal insufficiency was 19.2% (5 of 26) and 30.8% (8 of 26) when a peak stimulated cortisol level of < 18 μg/dL and < 25 μg/dL was defined, respectively. The prevalence was 8.3% and 28.6% in critically and non-critically ill patients; respectively, when a peak stimulated cortisol level of < 18 μg/dL was defined. Finally, when a peak stimulated cortisol level of < 25 μg/dL was defined, the prevalence was 16.7% and 42.9% in critically and non-critically ill patients, respectively.*
Conclusion: *Adrenal insufficiency in patients with AIDS is more prevalent than those without HIV infection, no matter what criteria of cortisol response after ACTH test are defined. An adrenal testing should be performed in all hospitalized patients with AIDS, both in critical and non-critical illness.*

Keywords: *Adrenal insufficiency, AIDS, HIV, Critically ill, Adrenocorticotrophic hormone (ACTH) stimulation test*

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The most common endocrine disorder in patients with human immunodeficiency virus (HIV) is adrenocortical dysfunction[1-4]. The involvement can occur at any level of the hypothalamus-pituitary-adrenal (HPA) axis, but the adrenal gland is the level most commonly involved. The possible etiologies include HIV, opportunistic infections, neoplasms, medications, autoimmune diseases, and peripheral resistance to glucocorticoids[1,5,6]. Autopsy studies have documented adrenal gland damage in as many as two-thirds of patients with acquired immunodeficiency syndrome (AIDS)[1,7,8]. However, adrenal insufficiency is rarely diagnosed in clinical practice because many patients have non-specific symptoms and signs such as malaise, weight loss, and hypotension, which cannot be distinguished from those caused by chronic HIV infection, opportunistic infections, or neoplasms. Therefore, the diagnosis requires a high index of suspicion and a confirmation by an appropriate laboratory evaluation.

During critical illness, several factors can impair the normal response of the HPA axis and complicate the evaluation of adrenal function[9-11]. There is controversy regarding the assessment of the HPA axis in critically ill patients. The insulin-induced hypoglycemia and the metyrapone tests are the traditional reference tests, but are rarely used in clinical practice because they are inconvenient and dangerous especially in the critically ill setting[1] The adrenocorticotrophic

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hormone (ACTH) stimulation test is usually used as a simple method for diagnosis of adrenal insufficiency, but there is no agreement on the dosage of corticotrophin used and the diagnostic criteria for interpreting the results[9,11,12]. There are two doses of ACTH used in ACTH test including the high 250-μg and low 1-μg ACTH tests. The traditional 250-μg test is thought to be a supraphysiological high stimulus resulting in circulating ACTH level of > 100-fold greater than a maximal stress level. Thus, this test may over stimulate the adrenal reserve, and mask the diagnosis of adrenal insufficiency. The low 1-μg ACTH test may be more accurate and result in more physiological levels of ACTH. However, several studies reported conflicting results of sensitivity and specificity between these two tests[9,11,12]. Traditionally, a serum cortisol of < 18 μg/dL, 30 or 60 minutes after the 250-μg ATCH test has been accepted as indicative of adrenal insufficiency. However, most patients can achieve the cortisol level between 25-30 μg/dL during critical period. Many experts advocate the normal cortisol response in critically ill patients should exceed 25 μg/dL.

The primary objective of the present study was to determine the prevalence of adrenal insufficiency in critically ill patients with AIDS by using the 250-μg ACTH test. The secondary objective was to compare the diagnostic criteria for adrenal insufficiency between cortisol response of < 18 mg/dL and < 25 μg/dL.

Material and Method

Patients

This prospective study was conducted in the Department of Medicine of King Chulalongkorn Memorial Hospital (KCMH), Bangkok, Thailand during October 1, 2003 and February 15, 2004. All adult patients with AIDS admitted to KCMH were eligible for enrollment into the present study. They were diagnosed with AIDS according to the CD4 count of < 200 cells/μL or AIDS-defining illness[13]. Patients, receiving corticosteroids within the previous three months, receiving medications known to interfere with the HPA axis, or with a history of HPA insufficiency, were excluded from the present study. Data of epidemiology, clinical characteristics, and treatment outcome including sex, age, HIV risk factors, present illness, Acute Physiology, Age, and Chronic Health Evaluation II (APACHE II) scores, length of hospital stays, and mortality were collected. Critically and non-critically ill patients were classified by the APACHE II scores of 20 or more and less than 20, respectively[14].

All patients signed an informed consent before enrollment to the present study.

Study protocol

To perform the 250-μg ACTH test, one vial of 250 μg synthetic ACTH (Cortrosyn, Organon Inc., NJ, US) was administered by intravenous bolus injection. The test was performed within 24 hours of admission. After administration, blood samples were drawn by venipuncture for cortisol levels at 30 and 60 minutes. All serum samples were centrifuged, and stored at 2 to 8□C for up to seven days. The cortisol level was determined by solid-phase radioimmunoassay (Diagnostic Products Corporation, Los Angeles, CA, USA).

The present study was approved by the Ethics Committee for Research in Humans from the University Hospital.

Statistical analysis

Descriptive data are presented as the mean ± SD unless otherwise stated. Unpaired Student's T-test and Chi-square test were used to compare continuous and categorical data, respectively with the SPSS program version 11.0 for Microsoft Windows. The statistical significance was set at $p < 0.05$ for all comparisons.

Results

Epidemiologic and clinical characteristics

There were 26 patients with AIDS (19 males and 7 females) with a mean age of 33.6 years (range: 22-46 years). The mean CD4 count was 75.6 (range: 1-321 cells/μL). At admission, none except patients 1, 20, and 25 were newly diagnosed with AIDS and non had ever received antiretroviral treatment (Table 1). Nine patients (34.6%) were hospitalized because of acute illness of less than seven days duration. At study time, the patients had a mean APACHE II score of 17.4 (range: 6-33). There were 12 and 14 critically and non-critically ill patients, respectively. The presenting illnesses were classified as opportunistic infection or neoplasm associated with HIV (25 patients), adverse effect associated with antiretroviral treatment (2 patients with lactic acidosis), and other conditions not directly associated with HIV or antiretroviral treatment (4 patients). The opportunistic infections and neoplasms included 13 mycobacteriosis (11 tuberculosis and 2 non-tuberculous mycobacteriosis), three cryptococcosis, three toxoplasmosis, two *Pneumocystis jirovecii* pneumonia, two cytomegalovirus (CMV) diseases, one salmonellosis, and one lymphoma. Other illnesses not directly related to HIV or antiretroviral treatment included one

Table 1. Epidemiologic and clinical characteristics, outcome, and results of ACTH test of each patient (n = 26) with AIDS

Patient	Sex, age (yr)	CD4 cell count (cells/μL)	Diagnosis	LOS (days)	APACHE II score	Outcome	ACTH test		
							Baseline	30'	60'
1	M, 39	123	Sleep apnea	42	23	Survived	5.8	10.1	12.4
2	F, 26	1	Salmonellosis	20	21	Survived	16.4	27.0	34.7
3	F, 34	ND	Toxoplasmosis and cryptococcosis	37	22	Died	22.4	29.0	39.4
4	M, 32	ND	Toxoplasmosis and GI bleeding	1	22	Died	32.0	42.9	36.8
5	M, 44	ND	*Escherichia coli* sepsis	1	21	Died	69.4	83.1	83.7
6	M, 27	ND	Tuberculosis with ARDS	2	33	Died	325.0	314.0	345.0
7	M, 23	ND	Tuberculosis, cryptococcosis, and staphylococcal sepsis	62	22	Died	25.0	25.1	25.5
8	M, 27	ND	Tuberculosis with ARDS	1	22	Died	78.1	76.5	70.9
9	M, 34	ND	Tuberculosis	4	25	Survived	24.5	25.6	24.8
10	M, 40	ND	Tuberculosis and sepsis	11	32	Died	31.8	33.6	35.1
11	M, 40	ND	Tuberculosis, cryptococcosis, and sepsis	26	32	Died	19.9	18.3	17.6
12	M, 38	63	Nontuberculous mycobacteriosis	8	25	Survived	30.1	29.2	28.6
13	M, 29	ND	PCP	6	15	Survived	26.6	43.2	55.2
14	M, 32	ND	Tuberculosis, chronic diarrhea	20	11	Survived	42.8	46.9	47.1
15	M, 36	ND	Nontuberculous mycobacteriosis	7	10	Survived	3.5	4.2	5.5
16	M, 42	97	Bullous erythema multiforme	47	8	Survived	13.1	29.4	36.7
17	M, 42	13	Tuberculosis	10	14	Survived	10.8	10.7	12.6
18	M, 30	ND	Tuberculosis	7	16	Survived	16.8	27.9	30.2
19	F, 22	6	Acute pyelonephritis	10	15	Survived	23.5	35.2	41.2
20	F, 35	ND	ART-associated lactic acidosis	10	9	Survived	13.9	32.5	39.2
21	M, 39	36	Tuberculosis and lymphoma	4	6	Survived	12.3	16.1	16.5
22	M, 34	ND	PCP	3	12	Survived	11.1	17.8	25.9
23	M, 46	16	CMV retinitis	14	9	Survived	11.3	18.4	17.5
24	F, 22	ND	CMV colitis and retinitis	29	7	Survived	7.5	13.5	18.2
25	F, 31	321	ART-associated lactic acidosis	7	14	Survived	18.2	33.6	34.6
26	F, 30	ND	Tuberculosis, toxoplasmosis	14	7	Survived	8.3	13.8	14.2

M: male, F: female, ND: not determined, LOS: length of stays, GI: gastrointestinal, PCP: *Pneumocystis jirovecii* pneumonia, CMV: cytomegalovirus, APACHE: Acute Physiology, Age, and Chronic Health Evaluation, ARDS: adult respiratory distress syndrome, ART: antiretroviral treatment, ACTH: adrenocorticotrophic hormone, 30': 30 minutes, 60': 60 minutes

sleep apnea, one bullous erythema multiforme, one acute pyelonephritis, and one *Escherichia coli* septicemia. All patients, who were diagnosed with adrenal insufficiency when a peak stimulated cortisol level of < 18 μg/dL, were treated with intravenous hydrocortisone. Eight (30.8%) critically ill patients died. In contrast, no mortality was observed in all 14 non-critically ill patients. The epidemiologic and clinical characteristics as well as outcome of the treatment are summarized in Tables 1 and 2.

ACTH stimulation test

The mean baseline, 30-minutes, and 60-minutes stimulated serum cortisol levels are shown in Table 2. The prevalence of adrenal insufficiency was 19.2% (5 of 26) when a peak stimulated cortisol level of < 18 μg/dL was defined (Table 3). In contrast, 30.8% (8 of 26) of the patients had adrenal insufficiency when a peak stimulated level of < 25 μg/dL was defined. When only critically ill patients (APACHE II ≥ 20, n = 12) were analyzed, the prevalence of adrenal insufficiency were 8.3% (1 of 12) and 16.7% (2 of 12) when diagnostic threshold of < 18 and < 25 μg/dL were used, respectively. In addition, the prevalence were 28.6% (4 of 14) and 42.9% (6 of 14) in non-critically ill patients (APACHE II < 20, n = 14) when diagnostic criteria of

Table 2. Summary of epidemiologic and clinical characteristics, outcome, and results of ACTH test of all 26 patients with AIDS

Factor	Number of patients (n = 26)*
1. Age (years)	
Mean ± SD	33.6 ± 6.8
Range	22-46
2. Male : female	19:7
3. Risk factors of HIV infection	
Intravenous drug use	4
Homosexual contact	4
Heterosexual contract	18
4. CD4 cell count (cells/mL)	
Mean ± SD	75.6 ± 10
Range	1.91-321 (n = 9)
5. APACHE II score	
Mean ± SD	17.4 ± 8.2
Range	6-33
6. Length of hospital stays (days)	
Mean ± SD	15.5 ± 15.9
Range	1-62
7. Acutely ill patients	9, 34.6%
8. Mortality	8, 30.8%
9. ACTH stimulation test (μg/dL)	
Baseline cortisol (mean ± SD, range)	34.6 ± 61.8, 3.5-325.0
30-minute cortisol (mean ± SD, range)	40.7 ± 58.7, 4.2-314.0
60-minute cortisol (mean ± SD, range)	44.2 ± 63.9, 5.5-345.0

* Data are calculated based on total number of 26 patients, unless otherwise indicated in parenthesis

Table 3. Prevalence of adrenal insufficiency in all 26 patients with AIDS, using different diagnostic criteria of peak stimulated cortisol

Diagnostic criteria[1]	Prevalence of adrenal insufficiency	
	N	%
Peak stimulated cortisol < 18 μg/dL	5/26	19.2
Critically ill	1/12	8.3
Non-critically ill	4/14	28.6
Peak stimulated cortisol < 25 μg/dL	8/26	30.8
Critically ill	2/12	16.7
Non-critically ill	6/14	42.9

[1] Critically ill patients were classified based on APACHE II score of ≥ 20

< 18 and < 25 μg/dL were used, respectively.

Discussion

The present study prospectively examined adrenal response to a high-dose ACTH test (250 μg) in 26 patients with AIDS, and evaluated clinical characteristics and treatment outcomes in both critically and non-critically ill patients. The prevalence of adrenal insufficiency depends on the diagnostic criteria used. The prevalence was 19.2 or 30.8% when a peak stimulated cortisol level of < 18 or < 25 μg/dL was defined, respectively. The present results are consistent with previous studies that reported the prevalence of adrenal insufficiency was high in patients with AIDS, compared to patients without AIDS[15-20]. Gonzalez-Gonzalez et al reported a 21.2% prevalence of adrenal insufficiency in patients with HIV infection, with a frequency of 26.4% and 9.4% in patients with AIDS and with asymptomatic HIV infection, respectively[15]. Wolff et al studied 63 patients with AIDS, and found that 19% had adrenal insufficiency[16]. Marik et al reported the prevalence of abnormal adrenal response in patients with HIV varying from 7% to 75%, depending on the criteria used[17]. Smolyar et al reported that the prevalence of adrenal insufficiency varied between 6% and 45%, depending on the doses of ACTH used[18]. Hoshino et al demonstrated 26.7% of 60 patients had abnormal adrenal function[19]. Piedrola et al retrospectively reviewed 74 patients with AIDS, and found that 22% had adrenal insufficiency[20]. In conclusion, adrenal insufficiency in patients with HIV infection especially in advanced stage (AIDS) is more prevalent than those without HIV infection, no matter what criteria are used to diagnose.

Assessment of adrenal insufficiency is very complicated in patients with AIDS. It is often difficult to exclude adrenal insufficiency based on the clinical ground alone because many patients with AIDS have symptoms and signs such as fatigue, weight loss, nausea, vomiting, and hypotension, which are indistinguishable from those with adrenal insufficiency[1-4]. Thus, the diagnosis of adrenal insufficiency depends on laboratory tests including the insulin-induced hypoglycemia, the metyrapone challenge, and the ACTH stimulation tests. However, the first two tests are rarely recommended because they are inconvenient, can be dangerous, and require patient hospitalization. For these reasons, the ACTH stimulation test has been widely used to assess the adrenal function. However, there is controversy regarding the dose of ACTH (1 and 250 μg), the peak stimulated cortisol level used to make the

diagnosis (18 and 25 μg/dL), and the difference of cortisol response between critically and non-critically ill patients[1,9,11,12,17]. The traditional cortisol response of > 18 μg/dL is derived from patients with non-critical illness. Several studies have shown that most critically ill patients can achieve cortisol level > 25 μg/dL[1,9,10,17]. Thus, the present study is the first to evaluate the prevalence of adrenal insufficiency between patients with AIDS in critical illness, in comparison with non-critical illness, by using both 18 and 25 μg/dL as the diagnostic criteria. The present results showed the prevalence of adrenal insufficiency were 8.3% and 28.6% in critically and non-critically ill patients, respectively, when a peak stimulated cortisol level of < 18 μg/dL was defined. In addition, when a peak stimulated cortisol level of < 25 μg/dL was used, the prevalence were 16.7% and 42.9% in critically and non-critically ill patients, respectively. The prevalence of adrenal insufficiency in patients with AIDS in critical illness is relatively high, compared to that of patients without HIV infection. Wolff et al reported the prevalence of adrenal insufficiency of 19% in critically ill patients with AIDS based on high-dose ACTH test[16]. Marik et al described the frequency of adrenal insufficiency of 7% and 21% when two diagnostic criteria of 18 and 25 μg/dL were used based on high-dose ACTH test[17]. Surprisingly, in the present study the prevalence of adrenal insufficiency in critically ill patients was less than that of non-critically ill patients, even though this difference was not statistically significant.

There are many potential reasons for the development of adrenal insufficiency in patients with AIDS. The destruction of the adrenal glands by infection, tumor, or hemorrhage is possible. Most patients in the present study had chronic opportunistic infections including 13 mycobacteriosis (11 tuberculosis and 2 non-tuberculous mycobacteriosis), 3 cryptococcosis, and 2 CMV diseases. Only one case had lymphoma. Chronic granulomatous inflammation due to *Mycobacterium tuberculosis* and *Cryptococcus neoformans* has been described to be associated with adrenal insufficiency[1,17]. CMV may involve the adrenal glands in 33% to 88% of patients with AIDS[1,17,21,22]. A role of CMV in adrenal insufficiency is controversial since most patients with CMV disease had symptomatic HIV infection, and thus may have other associated opportunistic infections involving the adrenal glands. In addition, most previous studies did not routinely investigate for CMV disease in all HIV-infected patients with adrenal insufficiency. Thus, well-designed controlled studies may be needed to clarify the association between CMV disease and adrenal insufficiency in patients with AIDS.

The plasma from patients in the setting of critical illness contains some mediators that impair the synthesis of corticosteroids[17]. In addition, the term "functional or relative adrenal insufficiency" has recently been described to reflect the notion that hypoadrenalism can occur without obvious structural defects in the HPA axis in some patients with acute, critical illness. Even though the cortisol level is high, it is insufficient to control inflammatory responses. Thus, treatment with supplemental corticosteroids may be beneficial in this group of patients. However, more well controlled studies are needed to clarify the existence of this term and specific situations in which corticosteroid replacement is of benefit.

Rifampin may predispose patients with AIDS to develop adrenal insufficiency. It induces the activity of the cytochrome P-450 enzymes, and thus increases the metabolism of cortisol. HIV may diminish the secretion of cortisol by the adrenal glands via the effects of cytokines like tumor necrosis factor (TNF). TNF is produced by macrophages which are stimulated by HIV infection[23]. It impairs corticotrophin-releasing hormone, ACTH, and adrenal cortisol synthesis[17,24,25]. In the present study, all patients with tuberculosis had received rifampin as a part of anti-tuberculous regimen.

In conclusion, adrenal insufficiency in patients with AIDS is more prevalent than those without HIV infection, no matter what criteria of cortisol response after ACTH test are defined. An adrenal testing should be performed in all hospitalized patients with AIDS, both with and without critical illness.

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ความชุกของภาวะต่อมหมวกไตทำงานลดลงในผู้ป่วยเอดส์ที่อยู่ในภาวะเจ็บป่วยอย่างวิกฤติ

วิชิต ประสานไทย, สารัช สุนทรโยธิน, ประสิทธิ์ เผ่าทองคำ, ชุษณา สวนกระต่าย

ความผิดปรกติที่พบบ่อยที่สุดในผู้ป่วยติดเชื้อเอชไอวี ได้แก่ การทำงานผิดปรกติของต่อมหมวกไต ความชุกของภาวะต่อมหมวกไตทำงานลดลงในผู้ป่วยเอดส์ยังไม่ทราบกระจ่างเนื่องจากความแตกต่าง ในการทดสอบขนาดของฮอร์โมน adrenocorticotrophic (adrenocorticotrophic hormone, ACTH) และเกณฑ์การวินิจฉัยที่ใช้ นอกจากนั้นยังมีปัญหาในการแปลผลการทำงานของต่อมหมวกไตในผู้ป่วยที่อยู่หรือไม่อยู่ในภาวะเจ็บป่วยอย่างวิกฤติ การศึกษานี้จึงมีวัตถุประสงค์เพื่อศึกษาความชุกของภาวะต่อมหมวกไตทำงานลดลงในผู้ป่วยเอดส์ที่อยู่และไม่อยู่ในภาวะวิกฤติโดยใช้การทดสอบด้วยการกระตุ้นด้วยฮอร์โมน ACTH ในขนาดสูง ผลการศึกษาพบ มีผู้ป่วย 26 รายที่เป็นผู้ป่วยเอดส์เป็นผู้ชาย 19 ราย และผู้หญิง 7 ราย โดยมีอายุเฉลี่ย 33.6 ปี และพิสัยระหว่าง 22-46 ปี ผู้ป่วย 12 และ 14 ราย อยู่และไม่อยู่ในภาวะวิกฤติตามลำดับ พบความชุกของภาวะต่อมหมวกไตทำงานลดลงเป็น 19.2% (5 ใน 26 ราย) และ 30.8% (8 ใน 26 ราย) เมื่อใช้เกณฑ์การวินิจฉัยโดยระดับคอร์ติซอลที่ถูกกระตุ้นสูงสุด < 18 และ < 25 ไมโครกรัมต่อเดซิลิตรตามลำดับ ความชุกเป็น 8.3% และ 28.6% ในผู้ป่วยที่อยู่และไม่อยู่ในภาวะวิกฤติตามลำดับ โดยใช้เกณฑ์ระดับคอร์ติซอลที่ถูกกระตุ้นสูงสุด < 18 ไมโครกรัมต่อเดซิลิตร และความชุกเป็น 16.7% และ 42.9% ในผู้ป่วยที่อยู่และไม่อยู่ในภาวะวิกฤติตามลำดับ โดยใช้เกณฑ์ระดับคอร์ติซอลที่ถูกกระตุ้นสูงสุด < 25 ไมโครกรัมต่อเดซิลิตร

โดยสรุปความชุกของภาวะต่อมหมวกไตทำงานลดลงในผู้ป่วยเอดส์มีอัตราสูงกว่าในผู้ป่วยที่ไม่ติดเชื้อเอชไอวีไม่ว่าจะใช้เกณฑ์การวินิจฉัยของระดับคอร์ติซอลที่ถูกกระตุ้นสูงสุดเท่าไรก็ตาม การทดสอบการทำงานของต่อมหมวกไตควรได้รับการทำในผู้ป่วยเอดส์ทุกคนที่รับไว้ในโรงพยาบาลไม่ว่าจะอยู่และไม่อยู่ในภาวะวิกฤติ