ASEAN Journal of Psychiatry

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- *Original articles:* This category is intended for full-scale basic or clinical studies. Original articles should not exceed 5,000 words (not including structured abstracts of up to 250 words, 3-5 key words, references, tables, and figures) with a maximum of 5 figures and 5 tables in total.
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Provide a context or background for the study (i.e., the nature of the problem and its significance). State the specific purpose or research objective of, or hypothesis tested by, the study or observation.

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The Methods section should include only information that was available at the time the plan or protocol for the study was written; all information obtained during the conduct of the study belongs in the Results section.

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Present your results in logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations. When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables.

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Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the Introduction or the Results section. For experimental studies it is useful to begin the discussion by summarizing briefly the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for future research and for clinical practice. Avoid claiming priority and alluding to work that has not been completed.

Acknowledgements

This section may include: i) acknowledgements of financial and material support; ii) contributions that need acknowledging but do not justify authorship; iii) acknowledgement of technical help; and iv) indications of previous presentation.

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10. *Personal author(s)*
• Murray PR, Rosenthal KS, Kobayashi GS, Pfaller MA. Medical microbiology. 4th ed. St. Louis: Mosby; 2002.
11. *Editor(s), compiler(s) as author*

• Gilstrap LC 3rd, Cunningham FG, VanDorsten JP, editors. Operative obstetrics. 2nd ed. New York: McGraw-Hill; 2002.

12. *Author(s) and editor(s)*

• Breedlove GK, Schorfheide AM. Adolescent pregnancy. 2nd ed. Wieczorek RR, editor. White Plains (NY): March of Dimes Education Services; 2001.

13. *Chapter in a book*

• Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. The genetic basis of human cancer. New York: McGraw-Hill; 2002. p. 93-113.

14. *Dissertation*

• Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant (MI): Central Michigan University; 2002.

OTHER PUBLISHED MATERIAL

15. *Newspaper article*

• Tynan T. Medical improvements lower homicide rate: study sees drop in assault rate. The Washington Post. 2002 Aug 12;Sect. A:2 (col. 4).

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17. *Dictionary and similar references*

• Dorland's illustrated medical dictionary. 29th ed. Philadelphia: W.B. Saunders; 2000. Filamin; p. 675.

UNPUBLISHED MATERIAL

18. *In press*

• Tian D, Araki H, Stahl E, Bergelson J, Kreitman M. Signature of balancing selection in Arabidopsis. Proc Natl Acad Sci U S A. In press 2002.

ELECTRONIC MATERIAL

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• Anderson SC, Poulsen KB. Anderson's electronic atlas of hematology [CD-ROM]. Philadelphia: Lippincott Williams & Wilkins; 2002.

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Contents

ASEAN Journal of Psychiatry 2007;8 (2):50.

AFPMH News

AFPMH and Regional Meetings of WPA

In the year 2007, the ASEAN Federation for Psychiatry and Mental Health (AFPMH) joined the World Psychiatric Association (WPA) Regional Meetings in Seoul and Shanghai between 18-20 April and 20-23 September, respectively.

At the WPA Regional Meeting in Seoul, the AFPMH had a symposium on "Teaching of Psychiatry for Medical Students in ASEAN: Sharing of Good Practices". There were 5 topics as follows:

1. Teaching of Psychiatry: Customising the Curriculum of Medical Students for ASEAN

   Prof. Pichet Udomratn (President, AFPMH)

2. From Psychiatric Services to Teaching of Psychiatry: Realigning of Objectives

   Prof. M Parameshvara Deva (Convener, AFPA)

3. What Makes a Good Medical Teacher?: Perception of Medical Students and Teachers

   Prof. Ee Heok Kua (National University of Singapore)

4. Undergraduate Psychiatric Education in Malaysia

   Prof. Hussain Habil (President, Malaysian Psychiatric Association)

5. Undergraduate Psychiatric Education in Thailand: Lessons Learned from Prince of Songkla University (PSU)

   Assoc. Prof. Sawitri Assanangkornchai (Editorial board, Journal of the Psychiatric Association of Thailand)

At the WPA Regional Meeting in Shanghai, the AFPMH had a symposium on "Globalization and Suicide in ASEAN: Sharing Good Practice for Suicide Prevention". There were 4 topics as follows:

1. Suicide and Suicide Prevention in Thailand

   Dr.Apichai Mongkol (Department of Mental Health, Thai Ministry of Public Health)

   Prof. Pichet Udomratn (President, Psychiatric Association of Thailand)

2. Suicide in Singapore: The National Response

   Dr. Hong Choon Chua (President, Singapore Psychiatric Association)

3. Managing Suicidal Patients: A Malaysian Experience

   Dr.Hussain Habil (President, Malaysian Psychiatric Association)

4. Suicide in the Philippines

   Dr. Dinah Pacquing-Nadera (Secretary-General, Philippines Psychiatric Association)

Both symposiums were arranged to support the hosting organizations, Korean Neuropsychiatric Association (KNPA) and Chinese Society of Psychiatry (CSP). These activities also strengthened the relationship between the AFPMH and both societies under the program called "AFPMH plus 3" (CSP, JSPN, KNPA) partnership program initiated by Prof. Pichet Udomratn, the current president of AFPMH.

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ORIGINAL ARTICLE

Personality profile among hypertensive patient undergoing pharmacological treatment in primary care setting

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Abstract
Objective: This study aimed to determine the association between the personality traits and social factors with compliance to anti-hypertensive pharmachotherapy. *Methods:* This cross sectional study was conducted from 1st of June until 31st of December 2004, which involved *Hospital Universiti Kebangsaan Malaysia* Primary Polyclinic in Bandar *Tasik Selatan, Cheras* and *Salak Polyclinic* in *Sepang, Selangor*. A total of 200 patients who fulfilled all the inclusion criteria, were selected as respondents. This study used the Mini International Neuropsychiatric Interview (M.I.N.I) for the psychiatric diagnoses and personality characteristics were assessed by using Personality Assessment Schedule (PAS) *Results:* The prevalence rate of non-compliance was 38.5%. Paranoid personality trait (27.3%) was the most common type of personality traits that associated with non-compliance to the medications prescribed. The results of this study revealed a statistically significant difference between drug compliance and age, race, gender and the site where the study was conducted. No association was found between patients' education level, occupation, income, marital status, family history of hypertension and personality traits and drug compliance. *Conclusion:* This study suggested that drug compliance among hypertensive patients was influenced by the presence of psychosocial factors. Hence, it is important for medical practitioners to understand these factors and administer treatment more individual.

Key words: *hypertension, non-compliance, personality*

Introduction

In Malaysia, it was estimated that about 14% to 25% of the population aged 15 years and above suffered from hypertension [1]. As blood pressure increases from normal to severe elevations, the risk for coronary heart disease, stroke, end stage renal disease and peripheral vascular disease increases markedly [2,3]. Anti-hypertensive drug therapy can reduce high blood pressure effectively and thus reduce the excess risk significantly. However, despite the existence of efficacious medications and improvements in awareness of hypertension, many patients in actual practice remain with uncontrolled hypertension. Hypertensive patients often experience poor compliance to treatment, a fre-

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quent cause of uncontrolled blood pressure.

Medication compliance has been defined in terms of an agreement between patient's behaviour of taking medications and the clinical prescription [4]. Compliance rates for many long-term drug therapies have been shown to be strikingly low, often no more than 40%-50% [5-7]. Non-compliance with medications is one of the major factors in the failure of therapeutic programs in patients having a chronic disease [4]. Non-compliance can contribute greatly to the variability observed in a drug's therapeutic effect if the clinician incorrectly attributes the patient's worsening condition to an absence of drug activity. This erroneous conclusion may lead to unnecessary diagnostic testing and changes in dose or regimen. Sub-optimal compliance can compromise the patient-provider relationship, because misconceptions about the effects of a therapy on the part of either the patient or the provider may lead to a breakdown in communication and negatively affect the patient's views about care.

Generally in Malaysia, the problem of blood pressure control is not lack of therapeutic options but due to patients' non-compliance. Lim and colleagues found out that 26% out of 168 of patients were not compliance to their medications [8]. Compliance to treatment depends on many factors, and no simple explanation for non-compliance exists. Potential determinants of compliance include sociodemographic characteristics, specific aspects of the treatment regimen (type, complexity, side effects, and duration), and features of the illness or potential illness (i.e., symptoms, duration, disability and medically defined seriousness) [9].

Elevated blood pressure has been associated with certain personality traits. Sommers-Flanagan and Greenberg (1989) found that hypertensive individuals were more likely to be characterized by difficulties with anger expression and interpersonal anxiety and frequently exhibited defence mechanism such as denial and repression [10]. Recent meta-analyses revealed conflicting findings in studies on the relationship between the blood pressure and personality [11,12]. Nevertheless, Jorgensen and colleagues (1996) reported that increased blood pressure and hypertension were associated with greater negative affect and defensiveness and less affect expression [11]. Rosmond and colleagues (2001) found out that a deficient dopamine D_2 receptor formation or action may contribute to hypertension via an increase of catecholamine release [13]. Paranoid and schizoid personality disorders are also associated with a polymorphism of the DRD2, which demonstrated low density of this receptor. A cross-sectional community survey in northern Japan found a relationship between personality and home blood pressure value [14]. Personality extroversion score positively affected the systolic blood pressure value, whereas no significant relationship was observed between personality psychoticism or neuroticism and blood pressure value. In other study, hypertensive patients had scored significantly higher in somatization, aggression/hostility and neuroticism [15].

Generally there is a lack of consensus on which personality or psychological traits related to the blood pressure [16]. The purpose of this study was to investigate the relationship between anti-hypertensive drug compliance with personality profiles. The results of the study may contribute to increase the awareness of health care providers particularly physicians on the issue of compliance and understanding their patients. These may aid to develop strategies for improvement of compliance.

Methods

The study was done after received approval from the Ethics Committee of Faculty of Medicine, Universiti Kebangsaan Malaysia and Research Committee of Psychiatry Department, Faculty of Medicine, Univer-

siti Kebangsaan Malaysia.. Those who were found to have psychiatric disorder were referred to the nearest psychiatric clinic for further evaluation and management.

Locations and subjects

This study was conducted at the *Universiti Kebangsaan Malaysia Hospital* (HUKM) Primary Polyclinic, *Bandar Tasik Selatan, Kuala Lumpur* and *Salak Polyclinic at Sepang,* Selangor. Primary polyclinic is a primary health care clinic of HUKM. It is situated in a 5-storey shop houses at *Bandar Tasik Selatan* commercial area. The total population for *Bandar Tasik Selatan* is 11,304. Of these, 5,944 (52.6%) were Chinese, followed by 4,365 (38.6%) Malays and 995 (8.8%) Indians. There were about 5,826 (49.2%) males and 6,016 (50.8%) females in this area [17]. It is an urban area, situated about 20 kilometers from the heart of Kuala Lumpur. Among the population, some of them were doing their own business, working at private companies or with the government agencies. The other centre is *Salak Polyclinic*, which situated in Selangor. It is a government polyclinic that is under the management of Ministry of Health, Malaysia. It is located about 48 kilometers from HUKM. It also provides primary health services. The total population here is 51,824. Of these 27,478 (53.0%) were Malays, followed by 13,262 (25.6%) Chinese and 11,075 (21.4%) Indians. This area is a rural area, majority of the populations' works as a farmer or at the palm oil or rubber plantations. As this place is near to the new Kuala Lumpur International Airport, many of the younger generation found their employment there.

This is a cross sectional study conducted at *HUKM Primary Polyclinic in Bandar Tasik Selatan* and *Salak Polyclinic in Sepang* from the first week of July 2004 to the last week of December 2004.

The sample population was all the hypertensive patients who attended the *HUKM Primary Polyclinic* in *Bandar Tasik Selatan* and *Salak Polyclinic* in *Sepang* during the study period. The sample size was determined using Epiinfo 2000 Statistical Package which was based on the power of study of 80% with alpha-level of 0.05 (95% confidence interval). Assuming and expected frequency of poor compliance towards anti-hypertensive pharmachotherapy in the population was around 26% [8]. The sample size was calculated to be around 197. An author had to divide her time to attend both clinics. To reduce the sampling bias the author attended the polyclinics on alternate days. Universal sampling was used in the recruitment process. All new and old hypertensive patients who came for their appointments at the time of the author presence at the respective polyclinics were approached.

The inclusion criteria included patients with essential hypertension, aged 40 years old and above, on anti-hypertensive pharmacotherapy for at least 3 months, agreed to participate in the project and could give written informed consent. They also must have sufficient command in Malay or English. The exclusion criteria included pregnancy, diagnosed to have secondary hypertension, no renal impairment (serum creatinine>125 mmoll/L) within the last six months of recruitment date, no impaired liver function tests (>3 times the upper limit of normal range), no concomitant disease such as diabetes mellitus, ischaemic heart disease, congestive cardiac failure, cerebrovascular accidents, bronchial asthma and chronic obstructive pulmonary disease. Patient's with blood pressure of 200/120 mmHg or more were also excluded.

Study instruments

1. Biodata and sociodemographic data: The variables included name, age, sex, marital status, occupation, total household monthly income, highest academic qualification, hypertension history (i.e., duration

of hypertension and family history of hypertension), history of smoking, alcohol intake, body mass index measurement and vital signs.

2. Mini international Neuropsychiatric interview (M.I.N.I): M.I.N.I was used to assess psychiatric diagnosis among respondents. It was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-IV and ICD-10 psychiatric disorders. The diagnosis is available in lifetime and 12 months version. M.I.N.I is a tool designed to meet the need for a short but accurate structured psychiatric interview that can be use in a variety of cultures, for epidemiological and clinical research purposes.

3. Personality Assessment Schedule (PAS): The personality profile of responders in this study was assessed by using the PAS [18]. It is an instrument designed to formalize the assessment of personality disorder. It may be used with any subject irrespective of psychiatric status. The instrument is a semi-structured, with the emphasis on the patient's premorbid status. The PAS is a standardized interview in which the interviewee is asked for information related to 24 personality characteristics, and where the answer is positive he or she is asked to provide examples of relevant behaviours. Ratings for each trait are made on a nine-point scale from 0-8, on which the ratings of 0-3 are trait accentuations in the absence of impairment of social functioning or distress to the subject or those around her. The scores are combined using formulae described by Tyrer *et al.* (1988) to derive either 13 personality disorder categories, or four summary categories [18]. The instrument also has been shown to possess adequate inter-rater and test-retest reliability and to be predictive of treatment outcome. The Kappa for this instrument was 0.65. The temporal and trans-cultural reliability is generally good to excellent. In this study, inter reliability assessment on assessing personality disorder/traits between researcher and her supervisor shows a good agreement between them with the Kappa of 0.7.

When the patient had fulfilled the inclusion criteria, written consent was obtained. The respondent was then interviewed by the researcher using the M.I.N.I. It was recommended that the screening schedule was used to make the diagnostic formulation of psychiatric problems. If this was not carried out there is a danger that the personality ratings will be contaminated by the mental state. They were then indulged in another interview, during which the researcher assessed their personality by using the PAS.

Outcomes

In the treatment of hypertension, a minimum compliance of 80% is generally needed to achieve an adequate reduction in blood pressure [8]. For this study, medication compliance is based on the pill counting, the compliance ratio is then calculated using the formula of Z/T, where X = known fixed number of tablet dispensed; Y = residual number of tablets in the container after eight weeks; Z = number of tablet that have been removed from the container; and presumably consumed (X-Y = Z); T = number of tablets which should have been consumed for a particular dose regime over the 8 weeks period. A ratio of 0.8 (80%) to 1.2 (120%) are used as the criteria for adequate drug compliance [24].

Data analysis

Data were analyzed by using the Statistical Package for Social Sciences (SPSS) Version 12.0. The relationships between the study parameters were analyzed using appropriate statistical tests.

Results

A total of 205 patients were approached to participate in the study. However, only 200 patients were qualified for the study. Out of 5 patients excluded from the study, 2 had difficulties understanding the interview and questionnaires because of language prob-

lems, 1 was later diagnosed to have diabetes mellitus and another 2 patients refused to participate in the study. Thus the response rate was 97.5%.

Table 1 shows the frequency distribution of sociodemographic variables of the respondents. The mean age for HUKM Primary Polyclinic was 54.7 (SD±8.5), while for Salak Polyclinic was 52.5 (SD±7.6). There was no significant difference in age between HUKM Primary Polyclinic and Salak Polyclinic (t=1.85, d.f=198, p=.071). Both centers had majority of Malay respondents, however *HUKM Primary Polyclinic* had more Chinese respondents (42.9%) as compared to *Salak Polyclinic* (4.9%). Most of the respondents (88.2%) were married. Majority of the respondents at *Salak Polyclinic* (77.8%) had total monthly income less than RM 1,500.00, whereas majority of the respondents at *HUKM Primary Polyclinic* (56.3%) had total monthly income more than RM 1,500.00. Respondents at *HUKM Primary Polyclinic* were more educated as 61.3% had at least secondary level of education and 17.6% had received tertiary education.

Table 2 shows that anxiety disorders were the most common type of psychiatric disorders (70.0%). Panic disorder was the most common form of anxiety disorders (40.0%). Only one respondent had agoraphobia without panic disorder (10.0%).

Table 3; shows that paranoid personality trait was the most common type of personality trait (25.5%), followed by anxious trait (21.0%) and sensitive aggressive trait (19.0%). The least trait presented was histrionic, and none of the respondent had sociopathic trait. Respondents from Salak Polyclinic (84%) had more single personality trait. HUKM Primary Polyclinic respondents (29.4%) had a high rate of multiple personality traits as compared to Salak Polyclinic respondents (16.0%). There was a significant difference between sites of study and number of personality traits (p<.05).

This study revealed that only 38.5% of the respondents did not compliant to the prescribed medications. *Salak Polyclinic* respondents had better drug compliance (53.7%) as compared to *HUKM Primary Polyclinic* respondents (46.3%). About 80.5% of the non-compliers were from *HUKM Primary Polyclinic*. There was a significant association between the sites

Table 1: Frequency distribution of study population by socio-demographic variables

Variables	HUKM Primary Polyclinic (n=119)	Salak Polyclinic (n=81)
Age		
40-49	37 (31.1%)	34 (42.0%)
50-59	51 (42.9%)	36 (44.4%)
60-69	26 (21.8%)	8 (9.9%)
70-79	4 (3.4%)	3 (3.7%)
80-89	1 (0.8%)	0 (0.0%)
Gender		
Male	64 (53.8%)	33 (40.7%)
Female	55 (46.2%)	48 (59.3%)
Race		
Malay	65 (54.6%)	71 (87.7%)
Chinese	51 (42.9%)	4 (4.9%)
Indian	3 (2.5%)	6 (7.4%)
Marital		
Single	6 (5.0%)	1 (1.2%)
Married	105 (88.2%)	77 (95.1%)
Widowed/ Divorced	8 (6.7%)	3 (3.7%)
Total Monthly Income		
<RM 1,500	52 (43.7%)	63 (77.8%)
>RM 1,500	67 (56.3%)	18 (22.2%)
Education level		
None	3 (2.5%)	6 (7.4%)
Primary education	22 (18.5%)	29 (35.8)
Secondary education	73 (61.3%)	41 (50.6%)
Tertiary Education	21 (17.6%)	5 (6.2%)
Occupation		
Employed	65 (54.6%)	39 (48.1%)
Unemployed	24 (20.2%)	11 (13.6%)
Retired	30 (25.2%)	31 (38.3%)

Table 2: Distribution of M.I.N.I. psychiatric diagnoses of the patients

Diagnosis	Number of cases
Dysthymia	3 (30.0%)
Panic disorder without Agoraphobia	2 (20.0%)
Panic disorder with Agoraphobia	2 (20.0%)
Social phobia	2 (20.0%)
Agoraphobia without panic disorder.	1 (10.0%)
Total	10 (100.0%)

Table 3: Frequency of personality traits among respondents according to centers

Personality traits	HUKM Primary Polyclinic (n=119)	Salak Polyclinic (n=81)
1.Sociopathic	0 (0.0%)	0 (0.0%)
2.Passive dependant	8 (6.7%)	9 (11.1%)
3.Anankastic	8 (6.7%)	3 (3.7%)
4.Schizoid	6 (5.0%)	2 (2.5%)
5.Explosive (impulsive)	12 (10.1%)	7 (8.6%)
6.Sensitive-aggressive	22 (18.5%)	16 (19.8%)
7.Histrionic	3 (2.5%)	0 (0.0%)
8.Asthenic	12 (10.1%)	3 (3.7%)
9.Anxious	28 (23.5%)	14 (17.3%)
10.Paranoid	36 (30.3%)	15 (18.5%)
11.Hypochondriacal	10 (8.4%)	6 (7.4%)
12.Dysthymic	11 (9.2%)	14 (17.3%)
13.Avoidant	8 (6.7%)	5 (6.3%)

and drug compliance with a probability of $p<.05$. There was also a significant difference in age between compliance and non-compliance respondents ($p<.05$). Majority of the respondents aged 60 and above were not compliant to the prescribed medication (52.4%). There was a significant difference in the drug compliance between male and female ($p<.05$). Female respondents (68.9%) were more compliant to the medication as compared to male respondents (53.6%). There was also a significant difference between the drug compliance and race with a probability of $p<.05$. Chinese respondents had a high non-compliance rate (52.7%) to the drug prescribed as compared to other races. Although single respondents had a high compliance rate (85.7%) to the drug prescribed, there was no significant difference in marital status with drug compliance ($p>.05$). There was no significant difference between the drug compliance and occupation ($p>.05$). Majority of the non-compliance (40.4%) were employed and had their own business. There was no significant difference between drug compliance and education level of the respondents ($p>.05$). Respondents with no formal education (44.4%) had high non-compliance to the drug prescribed. Respondents with total monthly income of more than RM 1,500.00 had high non-compliance (43.5%) as compared to the others. However there was no significant difference between drug compliance and total monthly income ($p>.05$). Respondents with no family history of hypertension had high compliance (64.6%) to the medication prescribed. However there was no significant difference between drug compliance and family history of hypertension ($p>.05$).

Table 5 shows that paranoid personality trait (27.3%) was the most common type of personality traits that associated with non-compliance to the medication prescribed, followed by sensitive aggressive personality trait (22.1%) and anxious personality trait (18.2%). This study also revealed that there was no significant difference between the number of personality traits and drug compliance ($p>.05$). However respondents with multiple personality traits had high drug non-compliance as compared to respondents with a single personality trait.

Discussion

The refusal rate for our research was low and a small percentage of subjects were

Table 4: Descriptive characteristics of sociodemographic data and drug compliance

Variable	Compliance	Non-compliance
Age		
40-59 (n=158)	103 (65.2%)	55 (34.8%)
>60 (n=44)	20 (47.6%)	22 (52.4%)
Sex		
Male (n=97)	52 (53.6%)	45(46.4%)
Female (n=103)	71 (68.9%)	32 (31.1%)
Race		
Malay (n=136)	90 (73.2%)	46 (33.8%)
Chinese (n=55)	26 (47.3%)	29 (52.7%)
Indian (n=9)	7 (77.8%)	2 (22.2%)
Marital status		
Single (n=7)	6 (85.7%)	1 (14.3%)
Married (n=182)	112 (61.5%)	70 (38.5%)
Others (n=11)	5 (45.5%)	6 (54.5%)
Occupation		
Employed & Business (n=104)	62 (59.6%)	42 (40.4%)
Unemployed (n=74)	60 (81.0%)	14 (18.9%)
Retired (n= 61)	40 (65.6%)	21 (34.4%)
Education level		
No formal (n= 9)	5 (55.6%)	4 (44.4%)
Primary (n=51)	32 (62.7%)	19 (37.3%)
Secondary (n=114)	70 (61.4%)	44 (38.6%)
Tertiary (n=26)	16 (61.5%)	10 (38.5%)
Monthly income		
< RM 1,500.00 (n=115)	75 (65.2%)	40 (34.8%)
> RM 1,500.00 (n=85)	48 (56.5%)	37 (43.5%)
Family history of hypertension		
Yes	92 (60.5%)	60 (39.5%)
No	31 (64.6%)	17 (35.4%)

excluded, thus it is unlikely to have bias in selection of cases. The respondent had an age range between 40 and 81 years old, with the mean age of 53.8 years old. Majority of respondents were aged 60 years old or less. *HUKM Primary Polyclinic* had more elderly respondents (≥60 years old) as compared to *Salak Polyclinic*. There is a possibility that the elderly living in rural area had a healthier life style and less stress environment as compared to the elderly in urban area. However this finding may also be due to the high awareness of the elderly in the urban area to seek treatment, whereas the elderly in the rural area rarely came for treatment as they always attribute the illness for ageing process. In rural area, most of the elderly lived with their spouses or on their own. As their children lived and worked in town, there was nobody to bring them to the clinic. The smaller number of respondents in age group 60 years old and above could also due to the exclusion of respondents with medical co-morbidity.

The gender distribution was almost equal between male and female respondents. This finding was consistent with the statistics from the Population and Housing Census of Malaysia (2000) [17]. Majority of them were married.

The ethnic composition of Malaysia comprised 65.1% of Malays, 32.0% of Chinese and 7.7% of Indians [17]. In this study,

Table 5: Distribution of drug compliance and personality trait

Personality	Compli-ance	Non-compli-ance
1..Sociopathic	0 (0.0%)	0 (0.0%)
2. Passive De pendant	12 (9.8%)	5 (6.5%)
3. Anankastic	6 (4.9%)	5 (6.5%)
4. Schizoid	5 (4.1%)	3 (3.9%)
5. Explosive (impulsive)	14 (11.4%)	5 (6.5%)
6. Sensitive aggressive	21 (17.1%)	17 (22.1%)
7. Histrionic	1 (0.8%)	2 (2.6%)
8. Asthenic	8 (6.5%)	7 (9.1%)
9. Anxious	28 (22.8%)	14 (18.2%)
10. Paranoid	30 (24.4%)	21 (27.3%)
11. Hypochon driacal	8 (6.5%)	8 (10.4%)
12. Dysthymic	17 (13.8%)	8 (10.4%)
13. Avoidant	6 (4.9)	7 (9.1)

majority of the respondents were Malays, followed by Chinese and Indian. In Sepang district, the Malays constitute 53.0% of the population, followed by Chinese (25.6%) and Indian (21.4%) and for this study, majority of the respondents of *Salak Polyclinic* were Malays, while the others were Chinese and Indian. This finding is not consistent with the distribution of ethnic population the district of Sepang, which this clinic serves. The possible reason could be that the Chinese and Indian have their preference to seek treatment from a nearby hospital in another district, which was fully equipped and a doctor could treat them. There were only one family physician and two doctors based at *Salak Polyclinic*. Besides running an out patient clinic at *Salak Polyclinic*, routinely the doctors also had to visit the other health centre in Sepang District. Thus, most of the time, the medical assistants would treat the patients, and the doctor only treat the complicated cases. The other reason for not including in this study is the language barrier. Majority of the respondents at *HUKM Primary Polyclinic* were Malays (54.6%), followed by Chinese (42.9%) and Indian (2.5%). This finding is also not consistent with the distribution of ethnic population in the district of Cheras that this clinic serves. Even though the Chinese population utilizing health services in HUKM Primary Polyclinic is high, most of them could not be included in this study because of language barrier.

More than half of the respondents in this study had at least secondary education with only 13.0% had attended tertiary education. Those with tertiary education and presumably with high income would prefer to seek treatment at private health centers where the clinic environment is more conducive.

Most of the respondents were employed or owned a business. *Salak Polyclinic* had more retired respondents (38.3%) as compared to *HUKM Primary Polyclinic* (25.2%). After the retirement certain people would prefer to stay in their own hometowns. They also would choose to live in rural area where life is less stressful and not so costly. Majority of the respondents had total monthly income less than RM1500 with most of them were from Salak, Sepang. *HUKM Primary Polyclinic* is a semi-public clinic where the service charge is much higher as compared to the fully subsidized public clinic like *Salak Polyclinic*. Thus majority of those who came to *HUKM Primary Polyclinic* were employed and had more income.

About three-fourth of the respondents had family history of hypertension. The prevalence of emotional disorders was 5.8% at *HUKM Primary Polyclinic* and 3.7% at *Salak Polyclinic*. The prevalence of psychiatric morbidity in this study is low in comparison to earlier studies in Malaysia. Maniam (1994) found the prevalence of emotional disorders in an urban private general practice of 29.9% [19]. Varma and Azhar (1995) found low prevalence of

depression (13.2%) and anxiety disorders (6.1%) in a primary health setting in Kelantan [20]. The prevalence of emotional disorders is higher in urban area as compared to rural area.

Hypertensive personality is among the most enduring constructs in psychosomatic medicine. The construct implies that there is an important relationship between psychological variables and the likelihood of developing high blood pressure. Despite the persistence of hypertensive personality construct, evidence substantiating its existence remains equivocal [21]. Hypertension has been associated with certain personality traits. Hypertensive individuals were more likely to be characterized by difficulties with anger expression and interpersonal anxiety, as well as frequently exhibited such defence mechanisms as denial and repression [10]. Research findings have shown that patients with hypertension score significantly higher on neuroticism and somatization traits [15, 22]. In this study, we found that majority of the respondents had paranoid personality traits (25.5%), followed by anxious trait (21%) and sensitive aggressive trait (19%).

Poor compliance with drug treatment is a barrier to effective management of hypertension. Compliance is seen as an active, intentional and responsible process whereby patients work to maintain their health in accordance with health regimens and in collaboration with health care professionals [23]. In this study, the counting pill method was adopted to measure medication compliance, where it was done manually. Every patient was given more medication than required for the period under study. The pills were counted without the knowledge of the patients, before it was given to them. The patients were then reminded to return the left over medication during the subsequent follow up. The tablets left in the container were count when returned. Therefore part of the success of this study depends on the trust of respondents to be truthful of their compliance. During this study, we noted that patients who wanted to avoid showing that they had missed doses might not return the unused medication. The usual reported range of non-compliance with medication is 25-50% [6]. In this study; the prevalence of non-compliance to the medication was slightly more than 1/3. This can be considered relatively low. The reason for this may be that medications have developed a great deal during the last decade. Therefore, they do not have so many side effects and are more effective than the predecessors. *HUKM Primary Clinic* respondents had a higher rate of non-compliance to the medication prescribed as compared to *Salak Polyclinic*. There was a significant association between these groups. There were few reasons that can contribute to this significant association. This significant difference may be explained by the logistic differences between these two study sites. *HUKM Primary Polyclinic* temporarily situated at a five-storey shop lot building at a busy commercial area. However, there was lack of public transportation for the patients as the bus/taxi and LRT stations were quite far from the polyclinic. Besides that there was not enough parking bay for the patients. The polyclinic environment is also not conducive for the patients as the clinic is always crowded, noisy and small, thus, most of the time, patients do not have a place to sit. At *HUKM Primary Polyclinic*, patients have long waiting time before and during appointments with their doctor. They were only able to see the doctor based on the appointments. Patients who had defaulted were asked to make a new appointment. On the contrary, *Salak Polyclinic* was cozier and less hectic. It is less crowded and has a large waiting area with comfortable chairs. It also has ample parking area and a bus station just outside the polyclinic area. Patients had shorter waiting time before and during appointments. The patients were allowed to see

their doctors if they had missed their appointments. Long waiting time before and during appointments with the physician are major reasons that the patients' give for failure to keep subsequent appointments, and these factors are indirectly affect their compliance to medications [24].

The relationship between the patient and his or her health care practitioners may affect drug compliance [25-27]. Specific physician practices and continuity of care may be important, and compliance can be improved by good relationships between the client and the health care provider [24]. The importance of enabling individuals to take an active part in planning their care together with the health care personnel was crucial. At *Salak Polyclinic*, the relationship between the health staff and the patients were closed. Most of the health staffs live around the polyclinic area and know most of the attendees. The doctors and medical assistant in this polyclinic are well known among the residents as most of them are local people and have been giving services for many years as compared to those in *HUKM Primary Polyclinic*. Most of the time at *HUKM Primary Polyclinic,* different doctors will treat the patients because the doctors were postgraduate students. A friendly environment and good relationship between the health care provider and the respondents at *Salak Polyclinic* might have contributed to the better compliance to treatment in these respondents.

Study by Monane *et al.* (1996) found that increased compliance was associated with advanced age (85 years and older) but another study found that age had no influence on compliance [28,29]. However Aziz *et al.* (1999) in their study found that older age group was statistically significant to be non-complier to the prescribed medication [30]. In this study there was a significant association between age and drug compliance, with majority of the respondents of the older age group (60 years and above) was noted to be non-complier to the prescribed medication. The reason for this may be that the elderly has memory problem and become forgetful, complexity of drug regimen and more medication side effects. Drug compliance among the elderly may be compromised by an increased number of prescribed medications, by decreased social support and by the increased incidence of memory problems in the population [31].

Majority of the respondents at *HUKM Primary Polyclinic* live in the city and have jobs, thus they were busy with earning their livelihood and hence forget to take their medication and attend clinic appointments. Unlike respondents from *Salak Polyclinic* where life is less hectic, they have more time to come for their appointments. The service and medication fees were much higher at *HUKM Primary Polyclinic* as compared to *Salak Polyclinic*, where the clients enjoy fully subsidized medical treatment. However, in this study there was no significant relationship between drug compliance with occupational status. There was a significant association between drug compliance and gender. Female respondents were found to be more compliant to the medication as compared to male respondents.

Aziz *et al.* (1999) in their study found that race was not seen to have influence on compliance [30]. However in this study, there was a significant association between drug compliance and race. The Chinese (52.7%) were found to be non-compliant to the prescribed medication as compared to the other major races. The reason could be that, majority of the Chinese in this study came from the urban area (94.4%). Based on the demographic data, most of them run their own business or work in private sectors, thus due to busy earned a living they might forget to take the medication. The other reason is that the Chinese community had strong believed on their

traditional medications, they like to take herbs, ginseng and other type of traditional medicine instead of the drug treatment.

In this study there was no significant association between drug compliance with marital status, educational level, income or family history of hypertension. Although there was no significant relationship between educational level and drug compliance, the respondents, who never had formal education, had a high non-compliance rate to the medication prescribed. The reasons for this may be that they are illiterate and have less knowledge and understanding about the illness. Respondents with income less than RM 1,500 had good compliance. There is a possibility that this group of people could not afford to fall sick, as they need to earn a living. If they fall sick, they could not work and have to spent the money on the treatment. Thus, it is better for them to comply with the medication in order to prevent complications of the disease.

Mental health generally has not been studied as a predictor of compliance among patients with hypertension. The idea of personality implies that people's attitudes and behaviours differ characteristically in ways that persist through changing situations and over long periods of time. These traits or habits are assumed to be largely unconscious approaches to the world expressed in everything a person thinks, feels, and does. Thus it caught the author interest to study the common type of personality trait among patients with hypertension. Although, it was found that respondents with multiple personality traits had poorer compliance, this study found no significant association between drug compliance with a number of personality traits. However, this study found that majority of the respondents with paranoid personality trait had poor compliance to the medication prescribed. A person with paranoid personality trait often has suspicion and mistrustful to others. There was a possibility that a person with paranoid personality trait thence has suspicion with the medication prescribed.

Nevertheless, in conducting this study, the researchers were aware of its limitations. Firstly was the relatively small sample size, which means that caution should be applied in generalizing these findings to the general population. It is recommended that home visits can be done to administer questionnaires at patients' homes or offices. Secondly, the place where the study was conducted also influences the results of the assessment. As mentioned earlier, in *HUKM Primary Polyclinic*, the clinic setting was not suitable to be a clinic as it is located in a shop lot space. The waiting area was too crowded and has not enough rooms to see patients. Thus, there was no proper place to interview the respondents. Sometimes the respondents were interviewed in the waiting area without any privacy when the consultation rooms were fully occupied. The respondents would be easily distracted by the noise. There were some patients who did not appear enthusiastic about the study despite their voluntary participation, given the fact that they had completed the responses in a rather short time. Thus, their reply may have been erratic and unreliable. Nevertheless, such patients were very small in number. Thirdly, the urban (*HUKM Primary Polyclinic*) and rural (*Salak Polyclinic)* cohorts may not be representative of the general population. Further studies are recommended to replicate these findings by using a bigger sample size.

The use of standardized interview schedule such as the PAS, has its limitation too. The main problem with the use of human interviewer is observer-bias [32]. There is a strong tendency for the interviewer (researcher) to have strong preconceived views or ideas about the hypothesis or research subjects, which may influence the clinical ratings. To minimize this form of bias, a second rater (supervisor) was called

in and the degree of agreement (kappa) calculated between the two.

Many methods have been used to measure compliance, each of which is limited by biases and methodological flaws [33]. The potential effect of the measurement itself, termed the "hawthorne effect," must be considered. This is the effect (often beneficial or positive) of observation itself on the outcome. Frequently, an individual's knowledge that he or she is under study influences behaviour and may therefore affects the compliance.

In this study, the researchers had the problem usually encountered in compliance studies, which results in an incomplete picture of compliance. Questionnaires were only received from patients who visited health providers. The patients with the poorest compliance do not visit the health care personnel and frequently do not participate in the study – therefore studied a self-selected population.

By identifying different "characteristic', "prerequisites" and "difficulties that describe compliance, it should be possible to make treatment more individual. It is also important for the individuals to understand that the significance of their own contributions. Health care systems have an important task in informing these individuals about their ability to affect their hypertension disease via their behaviour and treatment.

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ORIGINAL ARTICLE

The first methadone programme in Malaysia: overcoming obstacles and achieving the impossible

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Abstract
Objectives: To determine the best possible programme that suits our local setting, to determine the average dose required, and to determine possible problems that can arise from implementing such a programme locally and how best to address them. *Methods*: The inclusion criteria were those above 18, a positive urine test, the presence of a supportive carer and willing to engage in the programme. Methadone was initiated and observations relating to dose, adverse events, relationship with carers, work performance, crime and high risk behaviours were monitored for 18 weeks. *Results*: Two thirds of the 45 subjects completed the trial over the 18 week period. No significant adverse events occurred and improvement in relationship with carers and work performance were noted with reduction in crime and high risk behaviours. *Conclusion*: Methadone is a safe and effective drug that can be used in the local Malaysian setting.

Key words: *opioid dependence, methadone, harm reduction*

Introduction

Drug abuse in Malaysia is not a recent phenomenon. Though records show that locally, drug abuse dates back to the 8th century among Arab traders, the problem only escalated with the arrival of Europeans, especially during the British rule. Chinese migrant labourers, who were brought in to work in the tin mines, used opium in large amounts. Similarly, Indian migrants who were brought to work in plantations popularized the use of cannabis [1].

The period of drug use in Malaysia described above has been termed the "pre independence" period. The "post independence" period started in the 60's, when Malay youths gradually took over from Chinese as the main drug users [2]. Rapid progress and urbanization brought social, economical and political changes within the country, and being still fresh from independence, a strong 'British' influence still prevailed. Local youths joined their Western contemporaries in undergoing the cultural revolution of the 60's and in embracing the "hippie" movement. [1]. Around this same period, the establishment of "The Golden Triangle" in Burma, Laos and Thailand increased the supply of drugs to the surrounding areas, including Malaysia [3].

This problem escalated tremendously in the 70's and 80's, where from only 711 addicts identified in 1970, a total of 26,513 were identified in 1982 and, only a year later, this rose to 92,310 [1]. Finally on 19th February 1983, the Prime Minister declared

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that drugs, as the nations number one enemy, and a threat to national security [2]. The Drug Dependents (Treatment and Rehabilitation) Act was passed in 1983, allowing compulsory detainment of drug users for up to two years [4].

Currently, there is estimated to be 400,000 to 800,000 drug users in Malaysia [2]. Within the year 2000, 30,593 drug users were detected nationwide, whereby 14,850 (48.5%) were first time offenders and the remaining 15,743 (51.5%) were repeat offenders. The majority of those detected were males, (98.3%) and 65.9% were Malay. One of the main methods of treatment has been rehabilitating drug users in "Pusat Serentis" (Government run rehabilitation centres), where drug users can be detained for up to two years in accord with "The Drug Dependents (Treatment and Rehabilitation) Act, 1983". There are 27 "Pusat Serentis" all over the county which detains a total of 8,000 to 9,000 drug users at any one time. The drug users are detoxified 'cold turkey' and kept abstinent without any drug substitution for two years. This method has largely been ineffective, where less than 10 % of rehabilitated opioid dependence patients were able to eventually stay of drugs.

The current widespread recognition that the problem of drug usage brings about a wide array of social, economic and health problems has created more pressure from the public for the Government to review its treatment approaches and to give an increased role to health workers in managing heroin dependence patients. Corruption, accidents, prostitution and school drop outs have all frequently been associated with drug addiction [5]. Widespread substance misuse also depletes the human resources of a nation, as the majority of drug misusers are within the ages where they could be contributing to the nation's workforce. In Malaysia, 83% of drug users detected in 2000 were below the age of 40 years. Drug usage strains the nation's budget not only due to the loss of workforce, but also due to the cost of carrying out rehabilitation programs, health education and preventive programs, medical costs, legal costs and loss due to crimes. In Malaysia, the Government spends about RM 30 a day on each drug offender at all the rehabilitation centers. A history of imprisonment is common in heroin users in Malaysia. In the year 2000 lone, the total number of arrests under the "Dangerous Drugs Act" was 17,550.

However, it is the issue of health problems, particularly HIV, related to the use of intravenous heroin that has made the government and public sit up and realize the seriousness of the current situation. The number of HIV-positive people in Malaysia has increased dramatically in recent years. Since the first case of AIDS was detected in December, 1986, the number of HIV positive Malaysians has swelled tremendously. From only four cases in 1986, it has risen to a total of 992 cases by 1990 and 51,256 by 2002. Malaysia is a country with a HIV epidemic that primarily affects IVDUs. As of the end of 2001, 76 per cent of all reported HIV infections were to be found among IVDUs. The true figure may be much higher because HIV testing is only regularly done among drug users and sex workers rounded up in police raids.

Methadone maintenance was first developed as a treatment for heroin addiction in the mid-1960s [6] and has been proven to be an effective and safe mode of treatment [7,8]. Methadone maintenance has been proven beyond a doubt to be important in the reduction of the spread of HIV via intravenous drug use [9,10] and a leads to reduction in crime rates. Despite the overwhelming evidence on the benefits of methadone, and intense lobbying by certain quarters locally, it was only last year that methadone was registered locally for use in the treatment of opiate dependence. Even then, the criticism against its use continued and widespread resistance was still met. Many believed in total abstinence and

viewed methadone as just another drug. It was then that we decided to embark on this trial to gather local evidence that methadone can be a safe and effective drug to use in the treatment of heroin dependence in Malaysia. The objectives of this study was to determine the best possible programme that suits the local setting, to determine the average dose required in our local population and to determine possible problems that can arise from implementing such a programme locally and how best to address them.

Methods

Subjects were recruited by newspaper advertisements and word of mouth. The intended study population was the maximum recruited (not exceeding 100 subjects due to budget constraints) within an 18-week period. Each subject was to be followed up for 18 weeks (Day 0-126). The inclusion criteria set was those who were above 18, a confirmed heroin user (by urine test) and with the presence of a supportive carer, willing to engage in the programme and come once every 1-3 days for follow up and willing to buy methadone at their own cost after completion of the study (should they still require it). The exclusion criteria were concurrent use of medication that interacts with methadone and a grossly abnormal liver function.

During screening (Day 0), consent was obtained and physical examination, liver function test and drug urinalysis done. Demographics along with drug and criminal histories were noted. Relationship with carers was assessed using a visual analog scale, scored from 0-10. Eligible subjects would then undergo "Methadone Initiation" (Day 1), where they would arrive in the morning while experiencing withdrawals, and served with 10 mg methadone at 8 a.m. If withdrawals persist, additional doses of methadone would be served every 1-2 hours by 5 mg each time until there is a cessation of withdrawals.

Subjects would then enter the "Titration Phase" (Day 2-56). Dose can be adjusted on any day depending on presence of withdrawals or adverse events. Subjects with good social support may receive prescription for up to three days each time, hence need only to come every three days (with the condition that the carer handles the methadone). From Day 56-126 ("Reduction Phase"), a gradual reduction of methadone would be attempted at a dose reduction of 2.5 – 5mg a week. However, reduction is not mandatory. An attempt would only be made depending on patient's tolerability and confidence, and the investigator's judgement.

Throughout the 18 weeks, subjects would be assessed monthly regarding their relationship with their carers, work performance, high-risk behaviour and criminal activities. Random urine tests were also done monthly to detect concurrent heroin use.

Results

Study population

A total of 46 subjects turned up for screening, of which 1 patient was excluded due to grossly abnormal liver enzymes. Another 5 subjects dropped out after Day 0 (screening) and did not undergo methadone initiation. Therefore, only 40 subjects were given methadone, and results would be based on these subjects. Though it was initially planned to recruit 100 subjects, were had to stop recruitment after 18 weeks as initially planned due to budget constraints and ethical committee stipulations. We had initially expected to be able to recruit 100 subjects within the stipulated 18 weeks period, but eventually we were only able to recruit 46 subjects

The subjects were mainly males, consisting of 38 (95%) subjects, with only 2 females. Slightly more than half, 23 (57.5%) of them were married, 14 (35.0%) were single and 3 (7.5%) were divorced or separated. Only 23 (57.5%) of them were employed at screen-

ing (including 1 college student). More than half, 22 (55.0%) of the subjects had history of being detained in "Pusat Serenti" or jail for drug use or drug related offences.

Dropouts

There were 30 (75%) subjects that completed the whole course of the trial. One subject dropped out after 56 days after being hospitalized in another centre for tuberculosis and hence was withdrawn due to concomitant use of disallowed medication. (He still continued on methadone but was not included as part of the study). Another 9 subjects defaulted follow up, where most dropped out early within the first month. These 9 subjects dropped out after Day 3, 16, 22, 23, 29, 30, 41, 57 and 76 respectively. Efforts were made to contact these patients, where only 5 were contactable. Of these, 3 subjects said they were unable to commit to coming regularly due to work commitments and the other 2 admitted going back to heroin due to withdrawals and felt methadone was not helping them.

Doses of methadone

The daily dose of methadone required varied from subject to subject, ranging from 10mg a day to the maximum of 45mg a day. The average dose of methadone among all subjects also varied from month to month as illustrated below.

Adverse events

Only 2 (5%) of the subjects had complained of side effects. Both complained of pruritus of the face, which resolved after their methadone dose was divided into twice a day.

Random urine tests

As expected, all the subjects had a positive urine test for opiates at screening (Day 0). Thereafter, the proportion of subjects with a positive urine test rapidly declined until all were negative on Day 120, as illustrated below.

Relationship with carers

Out of the 40 subjects, 32 (80.0%) reported a better relationship with their carers, where else 7 (17.5%) reported no change. Only 1 (2.5%) reported a worsening relationship since the start of the programme.

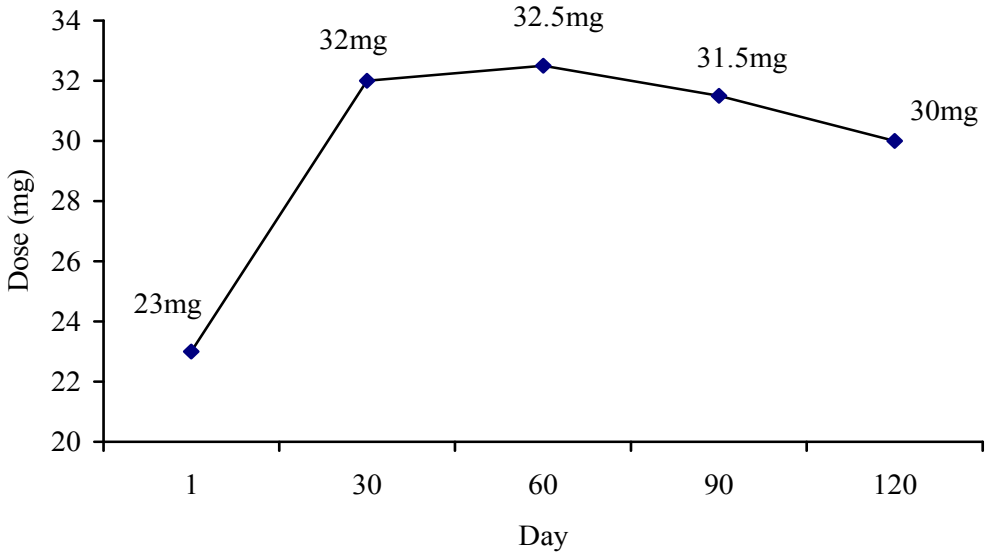

Figure 1: Average methadone doses

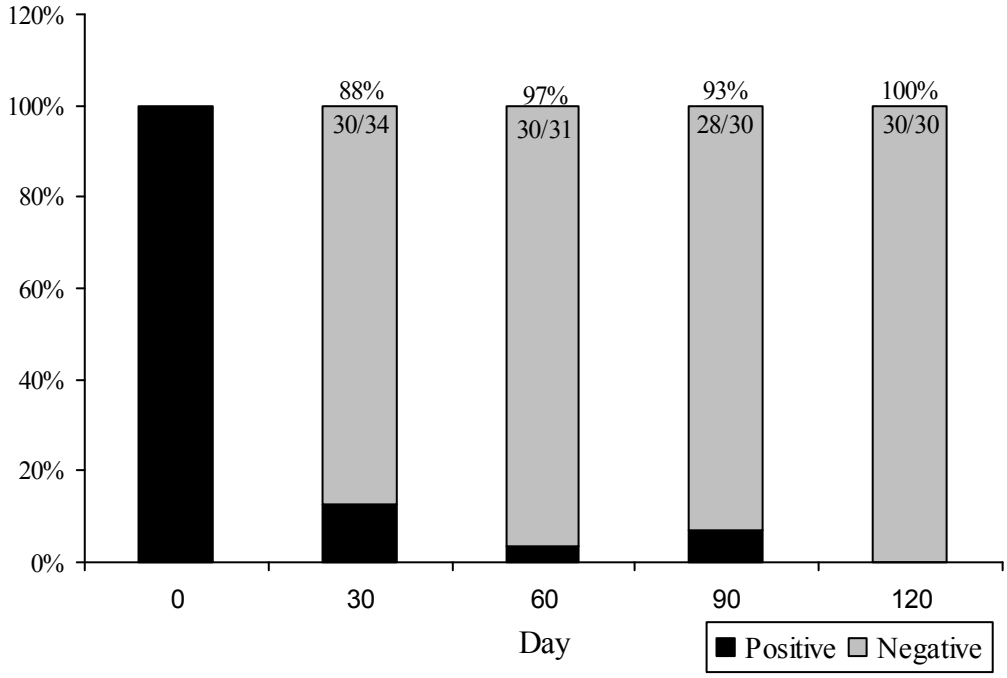

Figure 2: Percentages of positive and negative urine tests for opiates

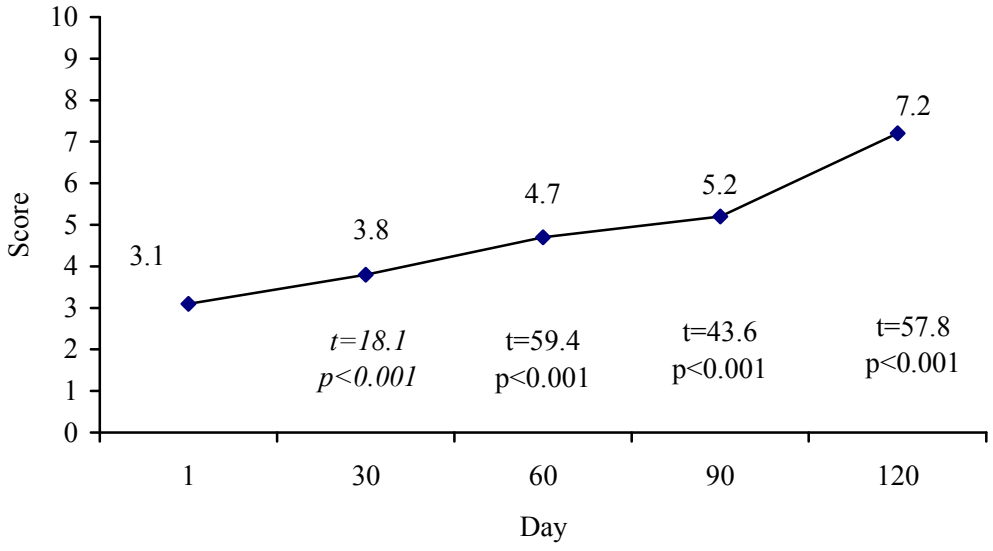

Figure 3: Average score of the relationship with carers on the Visual Analog Scale

As a group, the average score of how good their relationship with their carers gradually improved over time. Paired sample t-test was done to compare the scores with baseline and it was noted significant improvement was seen as early as Day 30.

Employment/work performance
Out of the 40 subjects, 24 (60%) reported an overall improvement in their work performance or had gained employment, where else 16 (40%) reported no change. None reported worsening work performance or losing their job since the start of the programme.

Out of the 17 subjects who were unemployed at entry into the programme, 8 subjects eventually found jobs (security guards, baker, car dealer etc) and 1 subject restarted studies again.

Crime/high risk behaviour
None of the subjects reported that they had been involved with crime or indulged in high risk behaviours such as self injecting or promiscuous unprotected sex since starting the methadone programme.

Discussion
As expected, the majority of the subjects were males, reflecting the pattern of heroin use in Malaysia. The fact that more than half of the subjects had a history of being detained in "Pusat Serenti" or jail for drug use or drug related offences was also not surprising as it is well recognized that the current system used for rehabilitating drug dependants had not achieved the desired results. The high rate of unemployment at screening was also expected, due to the disruptive and disorganized nature of lifestyle a heroin user leads.

The 75% retention rate achieved in this study was a heartening figure despite the rather short duration, as this was a pilot trial done with no prior experience on how to run such a programme in our local setting coupled with the overwhelming resistance from many areas. Out of the 10 "dropouts" one subject was excluded, though he was still on methadone, as he had taken anti-tuberculosis medication which was disallowed. For the purpose of this trial, concurrent use of medication that interacts with methadone is disallowed as one of the objectives was to determine the average dose of methadone that is required for our local population. Out of the remaining 9 "dropouts", 6 dropped out early, all within the first month. A valuable experience gained here was that if a subject were to default, he or she would most likely do so early. Therefore the initial period during the programme should be a time when close follow up and intense psychosocial interventions should be in place.

What was surprising from this study was the finding that the daily dose of methadone found in this study, 10-45 mg, was much lower that what has been found elsewhere. The average maintenance dose of methadone usually quoted ranges from 60-120 mg a day [6,7,11]. There are two possible explanations for this observation. Firstly, the quality of heroin used locally is extremely poor, frequently containing less than 10 % heroin. This could also explain the reason why the preference is to inject the drugs to get the desired effects. The other possible explanation for the low dose of methadone needed is the different genetic make up of our ethnic groups, as compared to the Caucasian population. This certainly would require further studies to establish if Asian do need lower doses.

This trial also showed that methadone is a safe drug when monitored, as only 2 subjects complained of side effects, which was mild and easily dealt with. This study also proved what many studies before had, that methadone can eventually lead to abstinence from heroin, and decreases high risk behaviours and crime, and improves work performance and relationship with carers. In this study the proportion of positive urinalysis gradually decreased over time. This could be explained that the optimal dose of methadone for someone needs some time to be established. Therefore positive urine tests, especially early on does not equate to failure on the subjects part. The subject should be reassured that this is the process he has to go through, and

should not be reprimanded. It is heartening that none of the subjects, or their carers reported that they had been involved with crime or indulged in high risk behaviours since starting the methadone programme. However, we must bear in mind that these are based on self reports This is in keeping with numerous other reports citing a reduction in injecting behaviour in those on methadone [12,13].

A majority of the subjects reported an overall improvement in their work performance or had gained employment. More importantly none reported the worsening of work performance or losing their jobs since the start of the programme, despite the very frequent follow-ups that they have to go through. Similarly, many reported an overall improvement in their relationship with their carers, similar to what other studies have shown [14]. Interestingly, one subject complained of a worsening relationship with his wife. This was caused by the fact that he was more stable and concerned about his wife's bad attitudes. In the past, he preoccupied with heroin use and did not care about his wife's behaviour.

Though we are producing results that have already been proven time and again, we feel it is still important as these has never been shown in our local setting. Local data such as this is extremely important in trying to convince the authorities in adopting new measures to abolish the drug abuse menace and the rise of HIV in Malaysia.

We do recognize some limitations in our study. Due to the budget constraints, the study population was small, and the follow up duration was rather short. A study with larger sample size and longer follow up period is warrant.

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ORIGINAL ARTICLE

Effects of CBT on children with disruptive behaviour disorders: findings from a Singapore study

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Abstract
Objective: The study examines the effectiveness of a CBT treatment programme over and above that of Treatment As Usual (TAU), with children who were referred to an outpatient child psychiatric clinic for disruptive behaviour disorders in Singapore. *Methods:* One hundred and three children aged 8 to 12 (mean±SD=10.22±1.31) who participated in the study were assigned to either the CBT+TAU (n= 51) or TAU group (n=52). Children in both the CBT+TAU and TAU groups received a standard and typical service offered to children at the outpatient child psychiatric clinic. In addition, children in the CBT+TAU group attended the CBT treatment programme that consisted of nine 1.5 hour weekly sessions. *Results:* Findings from ANCOVA indicated that children in the CBT+TAU treatment group showed significantly lower levels of aggression and significantly lower levels of parental stress at post-treatment and at 3-month follow-up in comparison to the TAU group. *Conclusions:* Findings from the present study provided some evidence of the effects of CBT in reducing aggressive behaviour and parental stress among children with disruptive behaviour disorders. Interpretation of the findings, recommendations for future research, and implications of the present study were presented.

Key words: *disruptive behaviour disorders, cognitive behavioural therapy, aggression, parental stress*

Introduction

Disruptive behaviour disorders are among the most prevalent disorders of childhood [1,2]. Children and adolescents with disruptive behaviour disorders often exhibit behaviours that are marked by severe aggression, violence, defiance, impulsivity, antisocial features, and even delinquency [3,4]. These disruptive behaviours cluster together and occur at higher rates than usual for children of the same age. Normal children may also exhibit many of the behavioural problems seen in children with diagnosed disruptive behaviour disorders, but their behaviour problems are fewer and occur less frequently. The difficulties of these disruptive disorders would pose fewer problems if most of these children grew out of their disruptive behaviours. However, studies found that over 90% of recidivist juvenile delinquents had disruptive behaviour disorders as children; and 40% of 7 and 8 year olds with disruptive behaviour disorders become recidivist delinquents as teenagers [5].

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Although not all children with disruptive behaviour disorders have persistent mental health problems to adulthood, it is one of the substantial risk factors for a lifetime of antisocial behaviour, social dysfunction, delinquency, substance abuse, poor peer relations, academic failure, and school dropout [2,6,7]. Disruptive behaviour disorders have been associated with severe, aggressive and antisocial behaviours that persist over the life course [1,8,9] and are often resistant to treatment [10,11]. Taken together, these studies suggest that disruptive behaviour disorders may result in enormous societal costs - a more violent society that brings about psychological, social, and economic consequences [12, 13].

Current literature suggests that stress within the parent-child relationship is often associated with behaviour problems in children [14,15]. Parents of children with disruptive behaviour disorders often reported high levels of child- and parent-related stress [16,17]. Parents who are highly stressed tend to have lower tolerance of children's misbehaviour, causing parents to behave negatively toward the child [18,19]. Almost inevitably, these aggressive, disruptive, and antisocial behaviours serve as a source of negative parent-child interactions. In addition, mothers of children with disruptive behaviour disorders tend to be more negative and directive, and less responsive to child initiations than mothers of non-disordered children [20]. These studies seem to suggest that the characteristics of children with disruptive behaviour disorders create an atmosphere of fear, negativity, and conflict that increase parental stress and undermine the quality of parent-child relationships [21].

As a result, disruptive behaviour disorders are among the most common reasons for referral to child mental health services [22, 23]. In Singapore, data obtained from an outpatient child psychiatric reflected similar trend. From 2001 to 2003, about 644 (31.1%) out of 2,072 children referred to the outpatient child psychiatric clinic in Singapore consisted of children and adolescents with disruptive behaviour disorders [24]. This finding indicated that disruptive behaviour disorders are most commonly seen at the outpatient child psychiatric clinic and is a rising concern in Singapore. Given the magnitude of the problem, intervention programmes that forestall the continuation of disruptive behaviour disorders and prevent its long-term consequences are especially crucial for countries like Singapore that depend mainly on human resources for growth and development [22-24]. As such, disruptive behaviour disorders in childhood or adolescence need to be taken seriously and addressed in Singapore.

Many researchers have suggested intervention programmes that are comprehensive and integrated, and directed toward these salient features of disruptive behaviour disorders [25,26] CBT has gained popularity due to its effectiveness and generalisability [27-29]. These intervention programmes for children and adolescents diagnosed with disruptive behaviour disorders have been based on our emerging understanding of the social-cognitive difficulties of these children [30,31]. Various studies have revealed these children often exhibit deficits in social cognition such as cognitive appraisal processes and interpersonal problem-solving skills [32,33]. These children tend to encode fewer interpersonal or environmental cues before interpreting the intention of the behaviour of others and tend to infer hostile intent especially in ambiguous situations [32,33] They were also found to generate more aggressive and ineffective solutions to interpersonal problems compared to non-disordered children [27]. These deficits may lead to poor impulse control, low frustration and stress tolerance, and limited insight of their own feelings as well as those of others. As a result, children with disruptive behaviour disorders may fre-

quently face frustrations due to a lack of skills on how to cope with their feelings and behaviour.

Hence, instead of focusing on the teaching of specific skills, the CBT treatment programme focuses on modifying the thought processes that support aggressive and antisocial behaviour and teaching problem-solving strategies [34]. Exposure to these skills enables children with disruptive behaviour disorders to enhance positive social interactions with family and peers, learn non-aggressive methods to resolve conflict, and adopt non-aggressive beliefs [35]. Findings from various studies examining the efficacy of CBT have also indicated classroom behavioural improvements, increased self-esteem, perceived social competence, and reductions in parents' or teachers' ratings of aggression following intervention [28,36]. Hence, it appears that CBT treatment programmes have the potential to generalise skills across settings [28,36].

Purpose of the study

This study hopes to determine the effects of the CBT treatment programme over and above that of Treatment As Usual (TAU) at post-treatment and whether gains made (if any), are maintained three months following the termination of the CBT treatment programme. We predicted that children in the CBT+TAU group would show significantly lower levels of aggression based on child and parent measures. In addition, children in the CBT+TAU group would show significantly lower levels of parental stress at post-treatment and at 3-month follow-up. There is a large body of research evidence documenting the effects of CBT treatment programmes in Western contexts but limited published research studies can be found in Asian contexts [37]. Hence, there are limited data to inform teachers, counsellors, and those in the child mental health services about strategies that work best for children with disruptive behaviour disorders. Importing Western intervention strategies without local verification and addressing issues relevant to the local context may not be appropriate and effective [38,39]. There is now increasing evidence that suggest the need for finding ways to improve the relevance and effectiveness of intervention programmes adopted from the Western context to the Asian context [39]. It is then important to investigate these issues in an Asian context like Singapore.

Methods

Participants

One hundred and three children who had been attending one of the local child psychiatric outpatient clinics for at least 6 months participated in the present study. These children were included only if they: a) were diagnosed by their attending psychiatrists (based on a semi-structured clinical interview and psychological assessment of the child) to have disruptive behaviour disorders such as Attention Deficit Hyperactivity Disorder (ADHD), Oppositional Defiant Disorder (ODD), or Conduct Disorder (CD), with or without a comorbidity of other disorders by the DSM-IV criteria [3,4], b) had a T-score more than 70 on the aggressive behaviour subscale of the Child Behaviour Checklist (CBCL) [40], c) were between 8 to 12 years old (Primary 2 to Primary 6), d) had parental consent and e) understood English and were English-speaking. In addition, children on medications were included in the study on the condition that no change of medication doses occurred one month prior to the participation and throughout the study.

The mean age for the sample was 10.2 years (SD=1.3). Eighty-six per cent of the participants were boys while the remaining 11.4% were girls. The racial composition was 89.5% Chinese, 5.7% Malay, 1.9% Indian, and 2.9% Others (which includes all other ethnic groups not listed). Self reported marital status of the parents were as follows: 83.8% were married, 2.9% were

separate, 10.5% were divorced, 1.8% were widowed, and 1% had never been married.

Measures

The Child Behaviour Checklist (CBCL) was designed to quantify a broad range of behavioural and emotional difficulties in children [40]. For the purposes of this study, the Aggressive Behaviour subscale of the CBCL (A-CBCL), which consists of 20 items that measure children's aggression from ages 4 to 18, was used. Parents were asked to rate how true each item was using the following scale: 0 (*Not true*) to 2 (*Very or Often true*). Sample items included "Argues a lot" and "Gets in many fights". All items on the A-CBCL were summed to provide a total score. Higher scores on the A-CBCL indicated higher levels of aggression. Previous studies have reported a Cronbach alpha value of .93 for the CBCL total score [41,42]. In the present sample, the Cronbach alpha value for the pre-treatment A-CBCL score was .89.

The Parenting Stress Index (PSI) is a scale that identifies stress within the parent-child relationships, and consists of two domains [43]. The PSI screens for dysfunctional parenting and predicts the potential for parental behaviour problems and child adjustment difficulties within the family system. The Child domain relates to the parents' perception in which the child may be perceived as stressful. The Parent domain relates to parents' view of their own functioning. For the purposes of this study, a total of 13 items from the Reinforces Parent (RE) (Child domain) and Attachment (AT) (Parent domain) subscales were used. The RE subscale measures the degree of parent-child interaction that results in positive affective response in parents. The AT subscale measures the level of motivation to fulfil the role of a parent. Parents were asked to rate the description on a 5-point Likert scale from 1 (*Strongly disagree*) to 5 (*Strongly agree*). Higher scores on the PSI indicated higher levels of stress within the parent-child relationships. Sample items included "My child rarely does things for me that make me feel good" and "Most times I feel that my child likes me and wants to be close to me." The PSI can be used with parents whose children are in preschool to 12 years of age. The reliability of the subscales used in this study are .83 for the RE subscale and .75 for the AT subscale [43]. Previous studies have also reported Cronbach's alpha values of .93 for PSI total score, .85 for the Parent domain and .91 for Child domain [44]. In the present sample, the Cronbach's alpha value for the total pre-treatment PSI score was .72.

Design and procedures

The current study was approved by the Institute of Mental Health's Clinical Research Committee and the National Healthcare Group's Domain Specific Review Board. Prior to conducting the study, the appropriate approval from parents (or guardians) of individual participants was obtained. Participation in the study was strictly voluntary and only children with parental consent were allowed to participate in the study. Written informed consent was obtained from the parents during the clinic visits, and research procedures were fully explained to the parents. All responses obtained were kept confidential.

Power calculations were done to determine the appropriate sample size. For a medium effect size of .50 to be statistically significant (at $p<.05$) approximately 80% of the time, a minimum sample size of 64 would be required [45]. Hence, the proposed target for the CBT+TAU group and the TAU group was 60 respectively. This estimation was based on the assumed attrition of 50%. Because the CBT treatment programme was to be delivered in the context of small groups consisting of about 6 to 8 children in each group, much time was spent for the participant recruitment. In addition, it was difficult to predict the number of participants to be enrolled into the study. Hence, because of these practical

constraints, random assignment was not fully possible. This resulted in the first 51 participants referred to the study to be in CBT+TAU and the next 52 to be in TAU.

CBT+TAU condition: Fifty-one participants in the CBT+TAU group attended nine 1.5-hour weekly sessions of the group-based CBT treatment programme conducted by the researcher [46,47] and individually administered Treatment As Usual (TAU) sessions once every 2 months on average. These children were assigned to 9 sub-groups that consisted of 6 to 8 children in each sub-group. The 9-week CBT sessions focused on: 1) Self-awareness, 2) Anger Coping Techniques, 3) Perspective-taking Skills, 4) Social Problem-Solving Skills, 5) Fighting Fair and 6) Prosocial Skills. It was delivered in the context of small groups (6 to 8 children in each group) and each session followed the same general format: (a) Review of previous lesson and homework, b) Introduction to a new set of skills, (b) Structured skills rehearsal, (c) Group activities, (d) Summary and homework assignment, and e) Presentation of rewards. In order to control for biases, parents and children had no prior knowledge about the CBT+TAU condition and were told that those assigned to the CBT+TAU group would be undergoing a series of 9 sessions to help them learn some useful problem-solving skills.

TAU condition: Fifty-two participants in the TAU group received individually administered TAU sessions, a typical form of intervention provided by the outpatient child psychiatric to children with disruptive and aggressive behavioural problems. The conventional therapy is usually provided by psychiatrists and consists of medication treatment and individual supportive therapy and parent training using behavioural techniques. Children who received TAU met up with the psychiatrist once every two months on average.

Treatment integrity: The integrity of CBT treatment programme was assessed in the following ways. First, the CBT treatment programme was conducted by the researcher, who holds a postgraduate degree in counselling. The intervention programme was manualised in order to adhere to intervention procedures. Second, the researcher conducted her first intervention group with the on-site supervisor, a consultant psychiatrist, as part of the direct supervision process. Third, both the researcher and on-site supervisor completed checklists that described the specific themes to be covered for each session. The correlation between researcher-rated and on-site supervisor rated protocol adherence was .95 (p<.001), Forth, the researcher documented children's progress and unique features of each session. Last, on-going clinical supervision and feedback were provided throughout the study through direct observation, review and discussion sessions with dissertation and on-site supervisor to ensure the adherence with intervention procedures and treatment fidelity.

Data analysis

Descriptive statistics were used to analyze the demographic characteristics of respondents such as age, gender, ethnicity, educational level, and parents' marital status from both the CBT+TAU and TAU groups. A series of Analysis of Covariance (ANCOVA) were used. All research participants, regardless of treatment drop-outs or missing data, were included in the intent-to-treat analysis. The intent-to-treat analysis was conducted with available pre-treatment data carried forward to replace all missing data at post-treatment and 3-month follow-up. The intent-to-treat analysis limited to 3-month follow-up was deemed appropriate [48].

Results

Preliminary analyses

Preliminary analyses of *t*-tests for continuous variables and chi-square for categorical variables were conducted to examine

whether participants in the CBT+TAU and TAU groups differed at pre-treatment on demographic characteristics. These analyses indicated no significant differences between the CBT+TAU and TAU groups in terms of their age, gender, ethnicity, education level, and parents' marital status. In addition, analyses from independent samples *t*-tests revealed no significant differences between the CBT+TAU and TAU groups at pre-treatment on all measures. Results of the evaluation of the assumptions of normality of sampling distributions, linearity, homogeneity of variance-covariance, and homogeneity of regression were deemed satisfactory. No significant differences were also found between the 9 subgroups of the CBT+TAU group at pre-treatment on all measures. The demographics of the research sample at pre-treatment based on gender, age, ethnicity, education level, and parents' marital status are presented in Table 1.

Treatment outcome

Table 2 shows the means and standard deviations for aggression as measured by the Aggressive Behaviour subscale of the Child Behaviour Checklist (A-CBCL) and the Parenting Stress Index (PSI) at pre-treatment, post-treatment, and 3-month follow-up [40,43].

Changes in aggression: Analysis of Covariance (ANCOVA) using pre-treatment aggression scores measured by the A-CBCL as the covariate revealed significant differences between the CBT+TAU and TAU groups on the A-CBCL at post-treatment, $F(1, 100) = 4.75$, $p=.04$. Results from the ANCOVA indicated that the CBT+TAU group showed significantly lower levels of aggression as measured by the A-CBCL than the TAU group at post-treatment.

Table 1: Demographics of research sample at pre-treatment

	Experimental (*n* = 51)	**Control (*n* = 52)**	**Total (*N* = 103)**	**Statistical Test**	***p***
Age				-1.91	*ns*
Mean	9.98	10.46	10.22		
SD	1.32	1.2	1.31		
Gender				97	*ns*
Male	43	48	91		
Female	8	4	12		
Education level				5.90	*ns*
Primary 2	8	4	12		
Primary 3	14	8	22		
Primary 4	9	16	25		
Primary 5	13	9	22		
Primary 6	8	15	23		
Ethnicity				4.39	*ns*
Chinese	43	49	92		
Malay	5	1	6		
Indian	1	1	2		
Others	2	1	3		
Parents' marital status				3.39	*ns*
Married	40	46	86		
Separated	3	0	3		
Divorced	6	5	11		
Widowed	1	1	2		
Never been married	1	0	1		

Table 2: Means and standard deviations for aggression and parental stress at pre-treatment, post-treatment and 3-month follow-up

Measure	Pre-treatment		Post-treatment		3-month follow-up	
	mean	*SD*	*mean*	*SD*	*mean*	*SD*
CBT+TAU						
CBCL	20.84	7.62	18.04	8.26	14.90	7.10
PSI	44.92	7.08	44.28	7.59	44.33	6.88
TAU						
CBCL	18.46	7.61	18.61	7.10	17.50	6.92
PSI	45.78	6.25	46.86	6.12	47.38	5.32

Note. A-CBCL = Aggressive Behaviour subscale of the Child Behaviour Checklist, PSI = Parenting Stress Index. Higher scores on the A-CBCL indicated higher levels of aggression while higher scores on the PSI indicated higher levels of parental stress.

Table 3: Analysis of Covariance (ANCOVA) at post-treatment and at 3-month follow-up

Source	***Post-treatment (1,100)***	***3-month follow-up (1,100)***
A-CBCL	4.75*	15.12**
PSI	5.18*	6.96**

Note. A-CBCL = Aggressive Behaviour subscale of the Child Behaviour Checklist, PSI = Parenting Stress Index.
*$p < .05$, **$p < .01$.

Similar ANCOVA analysis also revealed significant differences between the CBT+TAU and TAU groups on the A-CBCL at 3-month follow-up, $F(1, 100)=15.12$, $p=.001$. In line with our hypothesis, results from ANCOVA indicated that the CBT+TAU group showed significantly lower levels of aggression as measured by the A-CBCL than the TAU group at 3-month follow-up.

Changes in parental stress: ANCOVA using the parental stress pre-treatment scores measured by the Parenting Stress Index (PSI) as the covariate revealed significant group differences at post-treatment, $F(1, 100)=5.18$, $p=.03$. Results from ANCOVA revealed that the CBT+TAU group showed significantly lower levels of parental stress than the TAU group at post-treatment. Similar ANCOVA analysis also revealed that the CBT+TAU and TAU groups were significantly different from each other on PSI at 3-month follow-up, $F(1, 100)=6.96$, $p=.01$. Results from ANCOVA supported our hypothesis; findings indicated that the CBT+TAU group showed significantly lower levels of parental stress as measured by the PSI than the TAU group at 3-month follow-up. Results of the ANCOVAs are presented in Table 3.

Discussion

Findings from the present study revealed that the CBT+TAU treatment led to significant improvement in the level of parent-rated aggression in comparison to TAU at post-treatment and 3-month follow-up. The results of the study provided some evidence on the short-term effectiveness of the CBT+TAU treatment beyond that of Treatment As Usual in helping children with disruptive behaviour disorders to be less aggressive. Findings from the present study were in line with existing literature documenting the short-term effectiveness of CBT in producing improvements in parent ratings of aggression for severely

disturbed antisocial children in psychiatric inpatient settings and those in the school settings [28,36,49,50]. These findings indicated that the CBT+TAU treatment programme lead to improvement in aggressive behaviour across time, suggesting that the skills learned in the clinic were generalised to home settings and were maintained over time. In addition, improvements in aggressive behaviour suggest that children with disruptive behaviour disorders can be taught skills to respond to anger-provoking situations appropriately without resorting to aggression. The CBT treatment programme provided these children with the understanding of anger, effective anger coping skills, problem-solving skills, and perspective-taking skills that can alter their social-cognitive skills related to aggression before inappropriate behavioural responses occur.

Findings from the present study revealed that the CBT+TAU treatment also led to a significant improvement of parental stress in comparison to TAU at post-treatment and 3-month follow-up. High levels of parental stress are often evident in children with disruptive behaviour disorders [16,17]. This is because these children's disruptive and aggressive behaviours tend to be pervasive, and could lead to dysfunctional, coercive patterns in the family that are characterised by frequent yelling and punishment [51,52]. As such, parents often find it stressful to manage the aggressive and disruptive behaviours manifested by their children. With the evidence of reduced aggressive behaviours on parent measures of aggression at post-treatment and at 3-month follow-up, parents, perhaps, felt more competent, satisfied, and enhanced personally in their parenting role. These changes may have contributed to the significant improvements in the levels of parental stress in the present study.

While the limited support for the CBT+TAU treatment programme is noteworthy, findings on the positive outcomes on parent measures of aggression should not be over-interpreted. There is a tendency for parents to be "biased toward perceiving improvement following involvement in almost any intervention" [53]. Hence, the positive outcomes on parent measures of aggression may be a function of parent's biased or exaggerated reporting behaviour. In addition, the significant improvement on parent measures might be caused by the factors that were neither examined nor controlled, such as children's maturation and regression to mean amongst others.

Limitations

There are several limitations to the present study that should be acknowledged. One of the most apparent limitations is that the cognitive processes and mechanisms accounting for changes were not investigated. While findings from the present study revealed significant improvements on parent measures, conclusions about the changes in processes and mechanisms that accounted for significant improvements cannot be interpreted. Another limitation of the study derives from the use of a quasi-CBT+TAU design. The constraints imposed by the quasi-CBT+TAU study have been well documented [54]. Random assignment of participants into treatment groups was also not achievable in the present study because of constraints mentioned in the earlier paragraphs. In addition, it was not possible to blind parents as to which treatment their child was receiving because of the nature of the CBT program. Children in the CBT+TAU group had to attend 9 weekly sessions. Parents of children in the CBT+TAU also have access to workbooks that could easily allow them to identify the type of treatment that the child was in.

The sample employed in the present study represented a clinical-based sample of 103 children aged 8 to 12 and thus has limited generalisability. Hence, findings from these studies should be regarded as tentative until further replication studies are conducted on larger and more representative samples.

The present study relies heavily on parent-report of aggression, which may be subject to biases. Child aggressive behaviour reported by the parent may be influenced by a biased perception affected by child's negative reputation. It would be interesting to examine aggression from the child's and teacher's perspectives as they may have a very different perception of the behaviour.

Implications

Findings from the present study replicated and extended previous literature that is relatively sparse in demonstrating the effects of CBT treatments in reducing aggressive behaviour and improving parent-child relationships with Asian children clinically referred for disruptive behaviour disorders. Without well-controlled research and evaluation studies in an Asian context, researchers in Asia could be putting the children's mental health field at risk. Hence, it is hoped that findings from the present study serve as an impetus for future research efforts examining the effects of problem-solving based treatments among children with disruptive behaviour disorders in Singapore and other parts of Asia. This way, services and treatment programmes that are culturally appropriate can be developed to serve these at-risk children more effectively.

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ORIGINAL ARTICLE

Translation, validation and psychometric properties of Bahasa Malaysia version of the Depression Anxiety and Stress Scales (DASS)

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Abstract

Background: Up to date, there are handful questionnaires that have been validated in Bahasa Malaysia (BM). This study aimed to translate the Depression Anxiety Stress Scales 21-item (DASS-21) and measure its psychometric properties. *Objectives*: To determine the construct validity and acceptability of the DASS, BM. *Methods*: Two forward and backward translations were done in BM in accordance to guideline, and its validation was determined by using confirmatory factor analysis. A total of 263 subjects were selected by systematic random sampling to represent Malaysian population for reliability and validity purposes. *Results*: The BM DASS-21 had very good Cronbach's alpha values of .84, .74 and .79, respectively, for depression, anxiety and stress. In addition, it had good factor loading values for most items (.39 to .73). Correlations among scales were between .54 and .68. *Conclusions*: BM DASS-21 is correctly and adequately translated to Bahasa Malaysia with high psychometric properties. Further studies are required to support these findings.

Key words: *depression, anxiety, stress, reliability, validity, Bahasa Malaysia*.

Introduction

The Depression Anxiety Stress Scales (DASS) have been translated and in various languages and validated in different populations. The original version of DASS is 42-item. DASS 21-item is a modified and shorter version [1]. In this study, the authors focused on the effort of translating the DASS-21 into Bahasa Malaysia (BM) and eventually validated this version. The scoring of 21-item requires the users to time 2 of total score 21-item to suit the original 42-item. It is not a diagnostic questionnaire but rather as a severity measurement (dimensional rather than a categorical) [2]. DASS is suitable to be used in any clinical or non-clinical settings [3]. The questionnaire is easy and simple to administer to general population without any special training is needed. Unlike certain psychometric tests, by only using this questionnaire, researchers would be able to gauge levels of depression, anxiety and stress at the same time. Almost all 21 items in this questionnaire are relatively cultural free as none of its item mentioned any aspects on certain culture or religion. The effort of translation and validation of Bahasa Malaysia version were focused on DASS-21 before further development of BM DASS-42. Furthermore, DASS-21 is less been studied across the globe.

This study aimed to translate and validate the 21-item of DASS and to produce a well adapted BM version of 21-item DASS for

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Malaysian population.

Methods

Study design

This is a randomized multi-center cross sectional study. The process of translation, pre-test and validation of this project is summarized in figure 1.

A special permission from the original author of DASS (Peter Lovinbond) was also acquired before the commencement of this study. Informed consent was obtained from the participants after the nature of the procedure was fully explained.

Translation process of the DASS

Translation process was according guideline stipulated in US Census Bureau Guideline where 2 forward and 2 back translations were done in parallel by 2 medical and 2 language experts. This method was done to ensure the translated version would be grammatically sounded and the terms used were correct. At the same time, meanings and contents of original DASS were well preserved.

After the reconcilement of the two forward and back translations, sentence revision was done by all experts involved in the translation in meetings. Good translations were reflected by production of two English back translations which almost similar to original English version. At the end of this process, we produced a harmonized version of BM DASS-21 (BM-H).

Harmonized BM version was tested in a small group of people before authors embarked on real major validation study. Pretest was done on eight respondents with an objective to identify any flaws in harmonized version, which might affect the comprehension of the subjects. At the end of pre-test, we produced finalized BM version on DASS-21 (BM-DASS).

Validation study

The finalized BM version (BM-DASS) then was tested for its reliability and validity. Reliability in this study was determined by its internal consistency by looking at Cronbach's alpha values. Confirmatory factor analysis was used to ensure the validity of this BM-DASS by having acceptable factor loadings (>.4).

Selection of clinics and respondents

Study population of this study was a general population with age range between 14 to 55 years. The subjects were selected from 3 government clinics in Klang Valley area. A special permission was obtained from regional Ministry of Health authority. The selection of the clinics was done based on a few considerations. First, the attendees or patients that utilize these clinics should represent the composition of Malaysian population. Which means the location of clinic should not be in the areas that were highly dense with certain ethnic groups. It should not be at private clinics where certain economic class would affordable to acquire the treatment. At the same time, the convenience would also play an important factor. Participants were given information and consent forms prior to the study. Heterogeneous participants were taken care of in the aspects of age, gender, race and socio-economic class.

Selection of the subjects was also done at randomization where every third patients registered at the counter were chosen. A total of 263 subjects with various age groups and ethnicity were enrolled in this study. Composition of ethnic groups was tried to reflect the actual Malaysian population. Based on Malaysian Statistic Department (2005) where 54.1% were Malays, 25% were Chinese, 7.5% were Indians and 13.2% from other races [4].

Questionnaires

1. Demographic questionnaire: age, gender, ethnicity and level of education.
2) Finalized BM DASS-21Version.

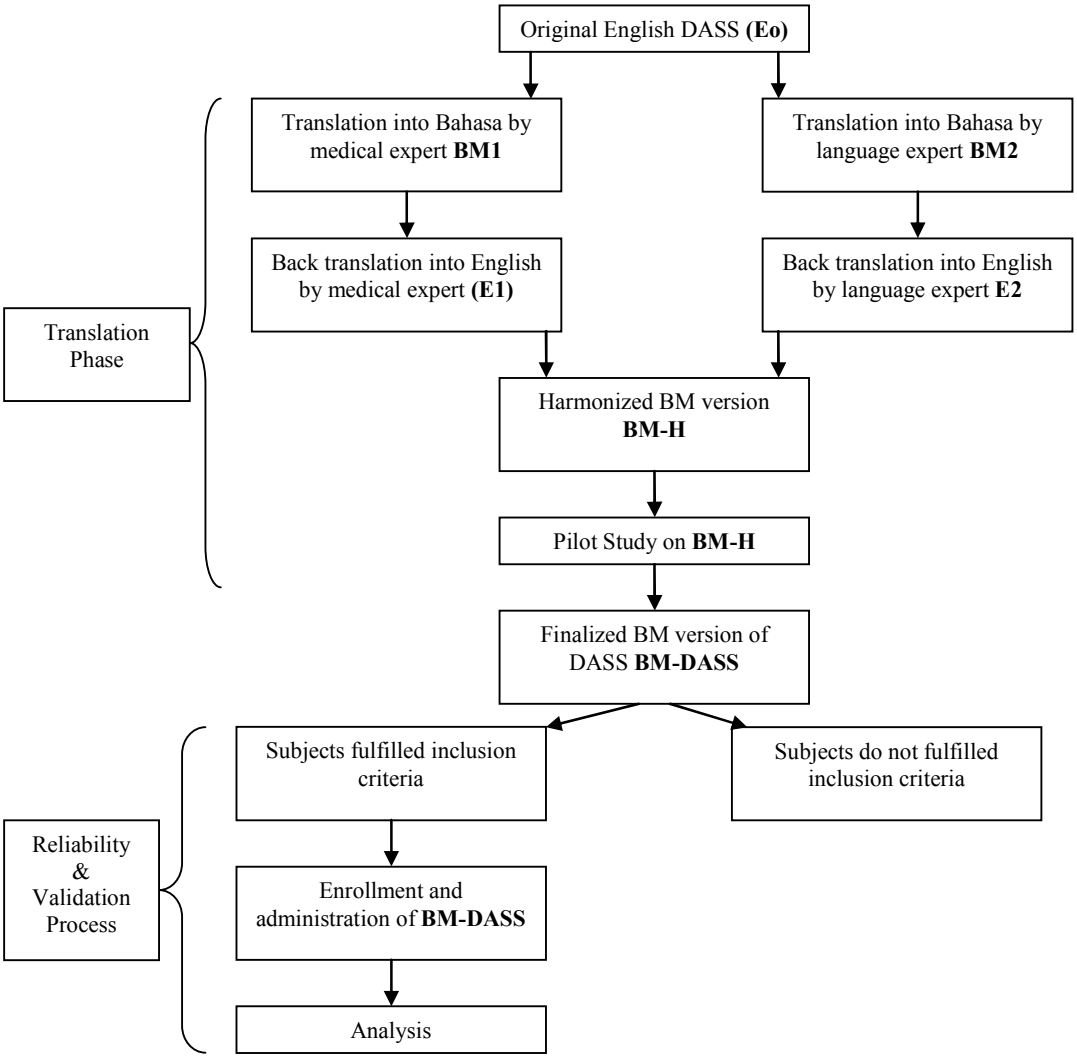

Figure 1: Overview of the whole process of cross-cultural adaptation and the validation of the DASS

.

The questionnaire was self-administered for the participants to answer. It took the maximum of 10-15 minutes for completion.

BM language fluency test.

In this study author created a simple BM language fluency test that can be administered on the spot, less time consuming and easy to assess. It involved building up a short sentence based on 3 words. This test required good grammar and wide knowledge of BM vocabulary in order to create a good sentence.

Steps taken to ensure the accuracy of responses

During the course of BM DASS questionnaire administration, the subjects should be left without any interference especially from facilitators of the project. If subjects raise any queries about the terminology, they should be explained as minimal as possible to maintain the objective of this study and it should be recorded. In actual process, author recorded only 8 subjects (3% of the total subjects) needed guidance

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in answering a few items.

Inclusion and exclusion criteria

1) Inclusion criteria:
   a) The age of the subjects was between 14 to 55 years.
   b) They must be proficient in BM.
2) Exclusion criteria:
   a) Subjects with any forms of cognitive impairments such as dementia and mental retardation would be excluded.
   b) Those were not able to give informed consent
   c) Subjects who were illiterate and had problem to understand BM and failed a short BM fluency test.

Results

Reliabilities of Bahasa Malaysia version DASS-21.

The reliabilities (internal consistencies) of BM DASS-21 were determined by looking at Cronbach's alpha values. Cronbach's alpha value for overall items was very good .904 (CI 95%). For depression, anxiety and stress scales the values were .84, .74 and .79 respectively.

Table 1 shows Malays and females were dominant in the aspects of ethnicity and gender. Chinese was underrepresented in this study as compared to actual population based on Malaysian Statistics Department Census (2005).

Validity test

The construct validity was evaluated by using confirmatory factor analysis. Factor loadings of 0.4 or more were considered good.

Tables 2 shows factor loadings for confirmatory factor analysis (CFA) of each item in BM DASS-21. From this table, it proved that BM DASS-21 managed to delineate its items into 3 main categories (depression, anxiety and stress). Three items had factor loadings less than .30. Among all items, item 18 was the poorest factor loading value (.20). This item "mudah tersentuh" (*I felt that I was rather touchy*) did not cross culturally sensitive to gauge stress level but rather had high factor loading for anxiety (0.65).

Items 7 and 12 had moderate factor loadings; .29 for anxiety and stress scale respectively. In comparison between depressive, anxiety and stress scales, depressive items were generally had good factor loadings (.51 to .73) as compared to other scales.

Correlations between scales were in the range of .54 and .68. There were high correlations between stress items with both depression and anxiety scales (.65 and .68 respectively).

Table 1: Socio-demographic data

	Number	**%**	**Total**
Age			
18-29	97	36.9	
30-39	115	43.7	
40-55	51	19.4	263
Race			
Malays	204	77.6	
Chinese	30	11.4	
Indians	27	10.3	
Others	2	0.8	263
Gender			
Male	100	38.0	
Female	163	62.0	263

Table 2: Item-total statistics

Item	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Q1-S	15.41	75.53	.58	.894
Q2-A	15.53	77.62	.33	.902
Q3-D	15.87	76.61	.52	.896
Q4-A	16.14	77.75	.45	.897
Q5-D	15.38	74.92	.56	.895
Q6-S	15.57	76.67	.46	.898
Q7-A	15.83	77.18	.39	.899
Q8-S	15.20	74.93	.53	.896
Q9-A	15.37	75.20	.48	.897
Q10-D	16.03	76.48	.53	.896
Q11-S	15.62	73.30	.71	.891
Q12-S	15.62	74.38	.67	.892
Q13-D	15.63	74.39	.63	.893
Q14-S	15.45	75.98	.49	.897
Q15-A	15.83	75.20	.66	.893
Q16-D	15.82	76.14	.53	.896
Q17-D	16.19	76.42	.60	.894
Q18-S	15.21	76.13	.43	.899
Q19-A	15.78	76.11	.49	.897
Q20-A	16.00	77.26	.50	.897
Q21-D	16.35	79.24	.50	.897

Discussion

Despite randomization in the selection of the subjects, this study had limitation in the aspect of study population. Its study population did not reflect the actual Malaysian population. Chinese were under represented as only 10% contributed to total population as compared to 25% according to Malaysian Statistic Department [4].

There are a few explanations to these outcomes. Firstly, the utilizing of government or public clinics is normally among Malays and Indians, Chinese generally are at a higher economic status and prefer to go to private clinics as they can afford the service costs. Secondly, we noticed that there were a large number of Chinese subjects selected during the randomization refused to participate or had language barriers. However, we did not have the exact percentage of the refusals.

Internal consistencies found in this study (.84, .74 and .79) were slightly low as compared to other studies; .92, .84 and .91 for DASS-21 Spanish version, .88, .82 and .90 for English DASS-21 in UK population and .81, .73 and .81 obtained by original author [5-7]. Retrograde analysis of three items (items 7, 12 and 18), which had poor factor loadings, revealed that these items were commented in pre-test as easy to comprehend but less specific to measure as purposed. Such as item 18 "mudah tersentuh" (*I felt that I was rather touchy*) was rather described the personality of an individual rather than psychological reaction toward unpleasant experience.

Correlations (inter-correlated) between scales obtained in this study (.54-.68) were slightly lower as compared to figures ob-

Table 3: Factor loadings based on confirmatory factor analysis for each item in BM DASS-21.

Item summary		**Subscale**		
		Depression	*Anxiety*	*Stress*
D3	perasaan positif (positive feeling)	.67		
D5	mendapatkan semangat (work up initiative)	.73		
D10	tiada diharapkan (nothing to look forward)	.56		
D13	sedih dan murung (down-hearted and blue)	.51		
D16	tidak bersemangat (unable to become enthusiastic)	.75		
D17	tidak berharga (wasn't worth)	.62		
D21	tidak bermakna (meaningless)	.57		
A2	mulut kering (dryness of mouth)		.65	
A4	kesukaran bernafas (breathing difficulty)		.55	
A7	menggeletar (trembling)		*.29*	.52
A9	panik dan membodohkan (panic and make fool)		.52	
A15	menjadi panik (close to panic)		.39	
A19	Tindakbalas jantung (action of heart)		.52	
A20	takut (scared)		.62	
S1	sukar ditenteramkan (hard to wind down)			.64
S6	bertindak keterlaluan (over-react)			.72
S8	tenaga cemas (nervous energy)			.58
S11	semakin gelisah (getting agitated)			.42
S12	sukar untuk relaks (difficult to relax)	.53		*.29*
S14	tidak dapat sabar (intolerant)			.56
S18	mudah tersentuh (touchy)		.65	*.20*

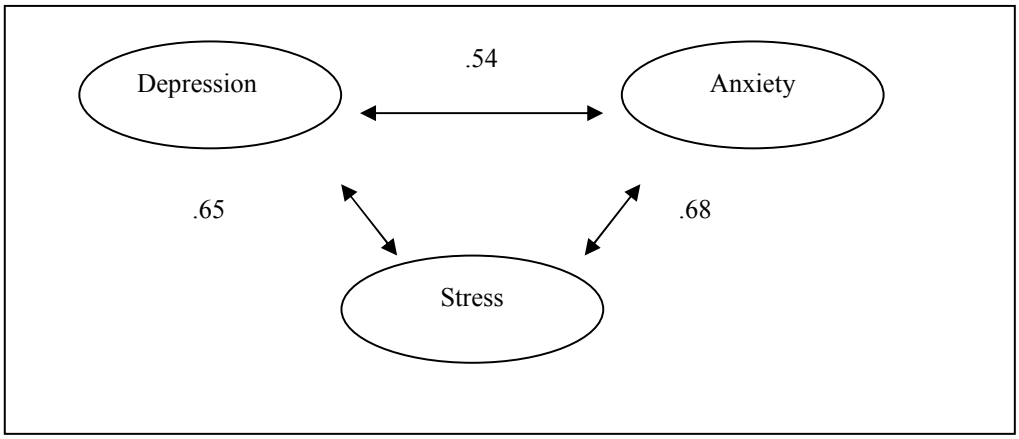

Figure 2: Correlation between the scales

Table 4: Statistical summary for each scale in BM DASS-21.

	Mean	Median	Standard deviation
DASS- 21			
Depression	4.2	3.0	3.4
Anxiety	5.0	5.0	3.3
Stress	7.4	7.0	3.7
Total score	16.5	15.0	9.1

tained in a study done by Crawford [3] where values of .74 to .77 were recorded and comparable with study done by original authors (.54) [7]. It was also documented that there were moderate intercorrelations (.5-.7) between the scales [1]. The correlations found in this study support the idea that 3 scales in DASS are intercorrelated, but we are not sure their actual relationships. These correlations can be causal in nature, such as genetic and other predisposing factors, or overlapping symptoms [7].

A comparison with clinical diagnosis would be interesting to be explored further since DASS anxiety scale is corresponded to various anxiety disorders in Diagnostic and Statistical Manual of Mental Disorders (DSM IV), the DASS stress scale corresponds closely to symptom criteria for GAD and the DASS depression scale corresponds closely to the mood disorders [1]. Theoretically, the stress symptoms are even overlapping between these entities [8]. Result of this study supports the tripartite model proposed by Clark and Watson. This is also inclining with original DASS theory where autonomic arousal is referring to anxiety where as hopeless and anhedonia are for depression. In this study, items such as “unable to become enthusiastic” (tidak bersemangat) and “wasn't worth” (tidak berharga) contributed high factor loadings for depression. There was also the presence of third dimension in the items, which was distinct from depression and anxiety. This was referring to stress subscale. Stress items would have loaded modestly on both for anxiety and depression factors, rather than forming a separate factor as they in fact do [7]. Factor analysis of this study supports this idea.

In developing a new instrument for Asian population, there is a high tendency that people express their psychological disabilities through somatic complaints as compared to western populations [9]. Prominent somatic complaints were not only noticed for depressive symptoms but also for stress and anxiety [10]. Author feels that any instrument intends to be used in Asian population should be culturally adapted and emphasized on somatic symptoms rather psychological in nature. These include body weakness and lethargic for depression which were not tested in this study. Breathing difficulty, dryness of mouth and action of heart items loaded quite good values in confirmatory factor analysis for anxiety in this study. These items are in autonomic arousal subscale of anxiety.

The present study is providing a preliminary milestone to the future development of BM DASS-21 version where some changes may be needful to achieve better results. Future research work is needed to look at other aspects for instance establishment of criterion validity BM DASS-21 where we can compare DASS scores with clinical diagnosis or with questionnaires that have been validated in Malaysian population such as Hospital Anxiety and Depression Scale. Other aspect is to look at psychometric properties among clinical samples and development of BM DASS-42. So far, we can say that BM DASS-21 is applicable for non-clinical population in Malaysia but not really for clinical samples. We would aspect it would be an equivalence or better result for clinical sample as proven in the previous studies [5,6].

This BM version may only applicable in west part of Malaysia and may not be for East Malaysia populations such as Kelantan, Terengganu, Sabah and Sarawak states

where they have different dialects.

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ORIGINAL ARTICLE

Obesity among patients with schizophrenia, attending outpatient psychiatric clinic, Hospital Universiti Kebangsaan Malaysia

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Abstract
Objective: This study aimed to determine the prevalence of obesity among patients with schizophrenia and its association with the demographic profile. *Methods:* This is a cross sectional study. Subjects were selected using systematic sampling. Patients attending the out patient psychiatric clinic, Hospital Universiti Kebangsaan Malaysia, who fulfilled the criteria and able to give consent were included in this study. Diagnosis of schizophrenia was made using Structured Clinical Interview (SCID) for DSM-IV. Demographic profiles of the patients were obtained and anthropometric measurements were measured and classified according to Body Mass Index (BMI) and Waist Circumference (WC) of Asian population. *Results:* A total of 97 patients were included. The prevalence of overweight (BMI: 23.0- 27.4 kg/m^2) was 39.2% (n=38), and the prevalence of obesity (BMI: >27.0 kg/m^2) was 35.1% (n=34). BMI was higher among non-Chinese (Malay and Indian, p=.03) and those who had low total household income (p=.03). Sixty-two patients (63.9%) had high WC, which was associated with male (p=.003) and non-Chinese (p=.03). *Conclusions:* Obesity is highly prevalent among patients with schizophrenia. The risk factors for obesity include male, non-Chinese and those with low total income. The high WC among non-Chinese and male patients suggests that they are at a higher risk of developing obesity-related physical illnesses. These findings support that obesity is a common critical issue among schizophrenic patients, and it warrants serious clinical interventions.

Key words: *schizophrenia, obesity, body mass index, waist circumference*

Introduction

There are increasing numbers of studies that documented high prevalence of obesity and metabolic abnormalities among psychiatric populations compared to general population [1,2]. Sixty-three percent of schizophrenic patients had metabolic syndrome [3]. In a study on 29,000 Malay-

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sian adults (≥20 years of age), 20.7% was overweight, while 5.8% were obese [4]. In the United State, the prevalence of obesity among general population was 20% to 30% [5]. Unpublished data of one year outcome from the National Mental Health Registry showed that 4%, 5%, 6.2%, 12.4% and 41.3% of 339 patients with schizophrenia gained weight for more than 20 kg, 15-20 kg, 10-15 kg, 5-10 kg and 5 kg, respectively [6]. Both men and women with schizophrenia had higher prevalence of obesity than their counterparts without schizophrenia [7,8].

The nature of schizophrenic illness (e.g., negative symptoms, social withdrawal, apathy, lack of motivation), as well as the patients sedentary life style, further increase their risks of obesity. Recent review suggests that approximately 40% to 80% of patients taking antipsychotic medications experience weight gain that exceed ideal body weight for 20% or greater [9]. Although the introduction of newer antipsychotic medications cause minimal side effects and improve cognitive function and improve quality of social functioning [10], these drugs however cause significant weight gain, especially olanzapine and clozaril, compared to typical antipsychotic medications [11]. Patients with schizophrenia both with the first episodes and those chronically exposed to conventional medications have been found to have more than three times as much intra-abdominal fat as controls matched for age, gender and lifestyle [12]. Thus, the magnitude of weight gain among them is very high, and this would in turn increase morbidity and mortality due to diabetes, heart diseases, hypertension and other obesity-related diseases [13-16] and finally would affect their quality of life. Prevention programs namely by regular routine monitoring of body weight, identifying risk factors and introducing wellness program in these patients are critical. The effective management of obesity requires a strong motivation and commitment from patients. This is significantly lacking in patients with schizophrenia. The other important factor is that the central acting anti-obesity drugs may induce psychotic episodes. These critical issues need further extensive studies and interventions. Thus, this study aimed at examining the prevalence of obesity and its associated demographic factors among schizophrenic patients attending psychiatric clinic, Hospital Universiti Kebangsaan Malaysia (HUKM).

Methods

This study was conducted at Psychiatric Outpatient Clinic, Hospital Universiti Kebangsaan Malaysia (HUKM) between April 2006 and July 2006. HUKM is a teaching, tertiary government hospital, located in the capital city of Malaysia. It receives referral from government clinics, i.e., district, primary health, and private clinics. Approximately 13 to 14 patients of schizophrenia are seen everyday.

The subjects were selected using systematic sampling. The diagnosis of schizophrenia were reviewed by researchers (a postgraduate psychiatric trainee and a consultant psychiatrist) using Structured Clinical Interview for DSM-IV Axis Disorder (SCID) [17]. The kappa, measuring the inter-rater agreement for this study, was one. The anthropometric measurements were assessed by a single examiner and standardized according to Malaysian Practice Guideline in Management of Obesity using beam balance (Health 0 Meter Kilopound Beam) and measurement tape. Body Mass Index (BMI) and Waist Circumference (WC) were classified according to Malaysian Practice Guideline, proposed by WHO to be used for Asian population [18]. BMIs of 18.5- 22.9 kg/m^2 , 23-27.4 kg/m^2, 27.5 kg/m^2.are considered normal, overweight and obese, respectively.

Waist Circumferences (WCs) of <80 cm and <90 cm are considered abnormal for female and male, respectively.

Inclusion criteria included patients who were able to give informed consent, aged between 18 to 60 years, had been on antipsychotic medications for at least one month and has sufficient command and understanding of either Malay or English and well literate. Diagnosis of schizophrenia was made on the SCID based on DSM IV diagnostic criteria. Exclusion criteria were patients who had mental subnormal or marked cognitive deficits, dementia, substance dependence, medical illness such as Cushing's disease, polycystic ovarian syndrome (PCOS), hypothyroidism, severe edema and pregnancy. Those received other medications contributing significant weight changes, e.g., steroid, insulin, orlistat, sibutramine, duromine, estrogen, were excluded. In addition, patients with BMIs less than 18.5 kg/m^2 were not included.

Statistical analysis

Comparisons were made using Student-t, chi-square tests (for normally distributed categorical data) and Mann Whitney U test (for not normally distributed data). ANOVA was used to compare multiple groups with normally distributed continuous data. Pearson and spearman correlations were used to measure degree of relationship between two continuous variables.

Results

Sociodemographic data

A total of 97 patients, who met the selection criteria, were included in this study,

Table 1: Socio-demographic characteristics of the respondents.

	Characteristic	**Total sample n=97(%)**
Gender	Male	44 (45.4)
	Female	53 (54.6)
Ethnic group	Malay	55 (56.7)
	Chinese	28 (28.9)
	Indian	14 (14.4)
	Others	0 (0.0)
Age (years old); mean±SD=32.0±15.5	<30	43 (44.3)
	30 to 39	30 (30.9)
	40 to 49	21 (21.6)
	>50	3 (3.1)
Marital status	Single	67 (69.1)
	Married	20 (20.6)
	Divorce	6 (6.2)
	Widow	4 (4.1)
Level of education	None	0 (0.0)
	Primary	0 (0.0)
	Secondary	58 (59.8)
	Tertiary	39 (40.2)
Occupational status	Employed	52 (53.6)
	Unemployed	45 (46.4)
Monthly household income (RM); mean±SD=1,500±1,500	low income (<1,500)	49 (50.5)
	middle income (1,500-3,500)	30 (30.9)
	high income (>3,500)	18 (18.6)

consisting of forty four (45.4%) males and 53 (54.6%) females. Fifty-five (56.7%) patients were Malays, 28 (28.95%) patients were Chinese and 14 (14.4%) patients were Indians. The characteristics of the respondents are shown in Table 1.

Prevalence

The prevalence of overweight (BMI: 23.0-27.4 kg/m^2) was 39.2%, whilst obesity (BMI: >27.0 kg/m^2) was 35.1% (Figure 1) and the prevalence of patient with high waist circumferences (WC: male > 90cm, female > 80cm) was 63.9%.

The association between obesity and patients' sociodemographic profile

- Age

Age of respondents had no association and relation with BMI (p=.28) and WC (p=.46).

- Gender

Mean WC of male respondents was 93.98±13.16 cm, significantly higher than mean WC of female respondents 86.78±10.22 cm (t=3.04, p=.003*). About 48.6% (n=17) of male and 51.4% (n=18) of female had normal WC, whilst 43.5% (n=27) and 56.5% (n=35) of male and female respectively had high WC (p=.633). However, the difference in BMI between male and female respondents were not significant (t=0.24, p=.81).

- Ethnic Groups

There was significant difference in the mean BMI between different ethnic groups (ANOVA: F=3.58, p=.03*). Chinese respondents (mean BMI =24.23±.09 kg/m^2) had significantly lower BMI than Malays (27.14±.32 kg/m^2) and Indians (27.06±.12 kg/m^2).

Household income

There was significant difference in mean total household income between patient who had normal weight (mean=RM 2,700 ±2,825) and obese (mean=1,300±1,025), (Z=2.78, p=.006). The total household income was found inversely correlated with WC of respondents (Spearman Correlation: rs=-.22, p=.03*) but not with BMI.

Occupational status

Of the total respondents, 52 (53.6%) respondents were employed and 45 (46.4%) were unemployed. 71.4% (n=20) of Chinese were employed while only 46.6% from non-Chinese respondents were employed. Employment rate among Chinese respondents were significantly higher than other ethnic groups (χ^2=5.03, p=.02*)

Occupational status of the patients had no association with the anthropometric measurements.

Educational level

There was no difference in BMI and WC of respondents in relation to educational level.

Discussion

Our findings indicate that overweight (34.5%) and obesity (33.8%) are highly prevalent among patients with schizophrenia. About 63.0% of the patients had high WC. These findings are three times and two times higher than the prevalence of general population in Malaysia [20] and global prevalence of obesity, respectively.

Other findings also found that schizophrenic patients are more obese than general population. Several reasons were given to explain, such as the nature of the illness, which lead to sedentary life style, lack of exercise, diet preference of taking high fat and low fiber diet and the effects of the medications [21,22]

To our knowledge, this is the first study in Malaysia examining the relationship between various anthropometric measurements in relation to patients' demographic profiles among schizophrenic patients, using the WHO classifications proposed for Asian populations (BMI and WC).

Three important socio-demographic factors (i.e., gender, WC; ethnic group, BMI and total household income, WC) were found significantly associated with obesity. These similar findings have been found by others [23,24]. The higher waist circumference

among males schizophrenic patients compared to female suggests that they are at the higher risk of developing obesity-related diseases. This is consistent with the findings that diabetic, hypertension and heart problems are highly prevalent among American males [25].

The preponderance of high BMI among non-Chinese may be due to various reasons. Culturally the composition of non-Chinese food contents high calorie ingredients, i.e., the used of "coconut milk", and ways of preparing the meal. Most Chinese food is steamed and boiled, while non-Chinese one is often fried. Majority of the Chinese are working compared to non-Chinese. However, there is no significant difference found between those who are employed and unemployed and obesity in this study, suggesting that their jobs are sedentary in nature. Low total income is associated with obesity, this could possibly be due to the lack of awareness on the importance of taking healthy balance diet, exercise, healthy life style and its relationship with health, obesity and chronic physical illness [26,27]. This may also suggest that patients with low total income are more likely to take food with high saturated fat and calorie as generally this nourishment is cheaper than food containing unsaturated fat and high calories [26,27].

BMI classification for Asian population proposed by WHO [18] were used in this study, but not the BMI values recommended for non-Asian. This is caused by the fact that Asian populations are at a higher risk of developing health problems at a lower BMI and have higher body percentage fat than non-Asian [29,30]. This risk would be even higher in schizophrenic patients, who are chronically on antipsychotic medications. Antipsychotics particularly atypical antipsychotics, e.g., olanzapine, clozaril, are associated with a high risk of metabolic syndrome [31]. Certain demographic factors are significantly associated with WC but not BMI and vise-versa, i.e., gender is associated with high WC but not BMI. This is because BMI is related to percentage of body fat, irrespective of the site of fat deposition. Whilst WC is associated with central obesity, it is an established indicator associated with metabolic diseases [3]. Since BMI is influenced by age, sex, composition of body muscle and population dependent, it is less accurate in predicting percentage of body fat as well as the risk of obesity-related diseases. Although BMI is commonly and widely used to estimate the body fat, WC is the most accurate indicator among the five anthropometric measurements [32,33]. WC should be measured especially in groups, who are at a higher risk of developing metabolic diseases, as in schizophrenic patients. Routine WC monitoring should be done on these patients.

This is a cross sectional study, the assessments were only done at one point in time. A prospective case control study should be carried out, including only new cases (for baseline data) and follow-up the patients to a certain period to examine the magnitude of weight gain. Prospective study would also help to ascertain the effects of duration of illness and antipsychotic medications on patients' body weight.

The subjects are hospital based. They are probably motivated patients and have better insight towards their illness, thus these findings may not reflect the community based population.

In conclusions, the overweight, obesity and high waist circumference are highly prevalent among patients with schizophrenia. Male, non-Chinese patients and low income are predictors of overweight and obesity. High waist circumference among schizophrenic patients particularly males and those from low income suggest that these patients are at a higher risk of developing obesity-related physical illnesses. Finally, these findings support that body weight is a common critical problem

among patients with schizophrenic, and it warrants serious interventions. Regular monitoring of patients anthropometric measurements, including, WC, medical and physical assessment, as well as metabolic markers, namely lipid and sugar profiles, should be done. Otherwise our objective in managing our schizophrenic patients that is not only to control their symptoms but also to ensure good quality of life would not be achieved.

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The prevalence of genital arousal disorder during sexual activity and potential risk factors that may impair genital arousal among Malaysian women

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Abstract
Objective: To investigate the prevalence of genital arousal disorder and the potential risk factors that may impair genital arousal among women at a primary care setting in Malaysia. *Methods:* A validated questionnaire for sexual function was used to assess genital arousal function. A total of 230 married women aged 18–70 years old participated in this study. Their sociodemographic and marital profiles were compared between those who had genital arousal disorder and those who did not. The risk factors were examined. *Results:* The prevalence of genital arousal disorder in the primary care population was 50.4% (116/230). Women with genital arousal disorder were found to be significantly higher in groups of more than 45 years old (p<.001), among the non-Malay (p=.01), those with lower academic status (p=.025), those married for more than 14 years (p=.001), those married to older husbands (aged>55) (p =.001), those having 4 children or more (p=.028), those having less sexual intercourse (less than 1–2 times a week) (p=.001), and those at post-menopausal state (p=.002). There was no significant difference between these two groups in term of salary (p=.29), suffering from medical problems (p=.32), dysmenorrhea (p=.95), menarche (p=.5) and hormonal replacement therapy (p=.6). *Conclusion:* Women with infrequent sexual intercourse are less likely to be sexually aroused (OR=0.29, 95% CI: 0.11-0.74).

Key words: genital arousal disorder, potential risk factors, Malaysian women

Introduction

Meaningful sexual relationship is one of the gratifying experiences enjoyed by couples. This could be achieved when normal sexual response cycle takes place during sexual activity [1,2]. Genital arousal in contrast to subjective sexual arousal has been a part of the cycle in the traditional as well as the contemporary models of sexual response cycle [3,4]. Difficulties in genital arousal, which constitute of lack of vaginal lubrication (LVL) [4], may prohibit orgasm, cause sexual pain and dissatisfaction. Lack of vaginal lubrication is not rare among women and in fact, it is considered as one of the major sexual health problems [5], especially with increasing age due to menopause or physical illnesses [2]. Lack of vaginal lubrication has been indexed as one of 7 dichotomous response items in sexual dysfunctions [6,7]. Given the variable correlation between genital vasocon-

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gestion and subjective sexual arousal in women with and without sexual dysfunction, there was a smaller subgroup of women who remain to able to be subjectively become aroused from a variety of non-genital stimuli [3,4]. The women with LVL reported loss of sexual excitement from genital stimulation and acquired loss of any awareness of genital congestion. LVL is a form of female sexual dysfunction (FSD) [4], which may result from multiple factors including anatomical, physiological, medical, psychological, cultural and social components [1,8,9].

The prevalence of LVL is estimated to be about 14% in western population [5]. Even though, this is lower than the prevalence of FSD in general, which ranges from 25% to 63% [10,11], it is nevertheless still high. Its prevalence in Asian countries is not known. However, it is possibly as high as that in the western countries, given the fact that the prevalence of FSD as a whole is also high at 30% [12].

In Malaysia, the whole area of sexual dysfunctions in women especially LVL is still largely uninvestigated [13,14]. This is despite clear need for the area to be explored, especially in the context of quality of life. Sexual problems among spouses have been reported to be the second leading cause for divorce between Malay Muslim couples. 'Wife not ready to have sexual intercourse' has been quoted as one of the reasons. This may be associated with lack of vaginal lubrication leading to sexual dissatisfaction and sexual pain [13]. It is noted that there have been increasing demands for clinical service related to sexual problems among men and women [13-16]. It is felt that women in this country still feel embarrassed to disclose details of their sexuality and sexual life and do not usually discus them openly [13,14].
While sexual problems among women have started to receive its due attention in the western countries, it is not the case in Malaysia [13,14]. To date, as far as our knowledge, there has been no study looking into the area in Malaysia [13]. It is the purpose of this study to explore this area in further detail.

The objective of this research paper is to investigate the prevalence of genital sexual arousal disorder during sexual activity and the potential risk factors that may impair genital sexual arousal in Malaysian women.

Methods
This was a cross-sectional study on women attending a primary health clinic. It was conducted over a period of four months (March to June 2005) at one of the government primary health care clinics located in Bandar Tun Razak, a rather busy suburban area of Kuala Lumpur. This study used a non-probability sampling (universal sampling) method.

Inclusion criteria included: i) female subject; ii) aged between 18 and 70 years old; iii) married and have a sexually active partner; iv) ability to read and understand the study languages (Malay or English) and (v) consent for participation in the study. Exclusion criteria included: i) chronic and severe medical illness/illnesses; ii) psychiatric illness/illnesses; iii) pregnancy iv) postpartum period of 2 months or less.The instruments used in this study were: i) sociodemographic and marital profile form; ii) the Malay version of Female Sexual Function Index (MVFSFI) and iii). the Mini International Neuropsychiatric Interview (M.I.N.I.).

Sociodemographic and marital profile form is a brief questionnaire was devised to obtain respondents' sociodemographic and marital information. It includes name, age, educational level, employment status, monthly family income, medical history, menstrual history, duration of marriage, age of husband, number of children and frequency of sexual intercourse. Malay Version of Female Sexual Function Index (MVFSFI) is a Malay translated version of the Female Sexual Function Index (FSFI) developed by Dr. Raymond Rosen. The original FSFI [17] is a 19-item, multidimensional self-report measure of female

sexual functioning. It covers 6 basic domains of female sexual functioning: *desire, arousal, lubrication, orgasm, satisfaction,* and *pain*. It is a validated questionnaire and has been shown to have discriminate reliability between women with and without female sexual dysfunction (FSD) and lack of lubrication [17,18]. The domain scoring for lack of lubrication is 7, 8, 9 and 10 with a minimum score of 0 and a maximum score of 20. The validation of MVFSFI took place at the same time of this study with the permission from the original author and was done in multiple aspects including the face, content, concurrent (criterion – specificity and sensitivity) and discriminant validity [19]. The reliability test for agreement using Pearson product-moment correlation coefficient (r) ranged from 0.767 to 0.973. The internal consistency using Cronbach's alpha ranged from 0.87 to 0.97. The cut-off score for lubrication domain (genital sexual disorder) was established at $\leq$ 10 for lack of lubrication (sensitivity 79% and specificity 87%). The lower the scores, the more likely the women would suffer from FSD [19]. A score of 10 and below on the domain of lubrication was taken as positive of having genital arousal disorder in this study. The Mini International Neuropsychiatric Interview (M.I.N.I.) was used to exclude any respondents with psychiatric illnesses from this study. This is a brief structured interview for major Axis I psychiatric disorders in DSM-IV and ICD-10. The inter-rater reliability for this study was ascertained by administering the instrument on 10 cases selected randomly. This was done by two of the authors and yielded a kappa value of 1.

Approval was obtained to conduct the study from the university ethical committee as well as from the administration authority of the particular clinic. All respondents who fulfilled the inclusion criteria were given an explanation about the study. A written consent was obtained from them. They were assured with regards to their anonymity and the confidentiality of the data obtained. A coding system was used to identify the respondents if it was necessary. The socio-demographic form and the MVFSFI [19] were given to each respondent to be filled up in a room with some privacy. After the MVFSFI was completed, each respondent was engaged in a clinical interview for diagnosing sexual dysfunction based on the DSM-IV criteria [20] and administered the M.I.N.I for exclusion of the other psychiatric illnesses. Those who were found to have sexual dysfunction were referred to a sexologist for further management.

Analysis of the data was done using SPSS 12.0.1 for Windows (SPSS Inc., 2003, Chicago). The relationship between the studies parameters were analyzed using appropriate statistical tests. Chi-square tests (χ^2 tests) were used to determine risk factors for FSD among categorical variables. Regression analysis using Multiple Logistic Regression (MLR) with 95% confidence interval (95% CI) was used to assess parameters that were actually considered as predictors of FSD.

Results

Two hundred and forty eight patients who attended the Bandar Tun Razak primary care clinic, Cheras, Kuala Lumpur were invited to participate in the study. However, 18 patients were unable to complete the study because of multiple reasons, such as unable to make time (4 patients), did not feel comfortable with the questions (7 patients) and did not bring their reading glasses to the clinic (5 patients). The response rate was 93% with total subjects of 230. By the use of MINI, two patients were excluded due to the positive screening and diagnosis of anxiety disorder and major depressive disorder.

The socio-demographic and marital characteristics of the respondents are shown in Table 1.

The studied urban women population was relatively of younger ages [mean of 39.2 years, SD=10.5], slightly younger than their spouses (mean of 42.7 years, SD=

11.3). They had a relatively high level of educational background (almost all had received at least primary level of education and still a majority had received at least secondary education). The Malays predominated other races (76.1 %) as compared with Chinese (13.9%) and Indians (8.7%). This was, however, quite representative as the whole population of the area. Most of them come from the lower middle socioeconomic status, judging from their income levels. This was explained by the fact the richer ones would expectedly visit the private practitioners who would offer more flexible visiting times.

The mean duration of marriage among these women was 15.5 (SD=11.3) years. More than half of them (66.7%) were from the pre-menopausal group. Majority of them (43.5%) had between 2 to 5 children, 40% had less than 2 and 16% had more than 5 children. Only 10% of the women had sexual intercourse of less than one time/month; 32.2% of them had it 1-2 times/month; a majority of them (44.3%) had it 1–2 times/week; and 13.5% had it more than 2 times/month.

Out of 230 respondents interviewed, 116 of them scored $\leq$ 10 on genital arousal (lack of lubrication, LVL) domain of MVFSFI. The prevalence of women with genital arousal disorder (LVL) was 50.4% (116/230).

The risk factors associated with women suffering from genital arousal disorder are shown in table 2.

Genital arousal disorder was found to be significantly more common among women who were over 45 years old (χ^2=12.3.0, p <.001), the non-Malays (χ^2=6.5, p=.01), those with lower academic status (χ^2=5.04, p=.025), those who were married for more than 14 years (χ^2=11.0, p=.001), those who married to an older husband (aged > 55) (χ^2=11.9, p=.001), those having 4 children or more (χ^2=4.52, p=.028), those having less frequent sexual intercourse (less than

Table 1: Sociodemographic and marital characteristics of the 230 respondents

Variable	Characteristics	*n*	(%)
Age (year) (mean±SD= 39.2±10.5)	< 30	50	(21.7)
	30-39	82	(35.7)
	40-49	56	(24.3)
	≥ 50	42	(18.3)
Race	Malay	175	(76.1)
	Chinese	32	(13.9)
	Indian	20	(8.7)
	Others	3	(1.3)
Education level	None	2	(0.9)
	Primary	53	(23.0)
	Secondary	142	(61.7)
	Tertiary	33	(14.3)
Family income (RM/month) (mean±SD= 2,165±1,552)	<1000	30	(13.0)
	1000-1999	92	(40.0)
	2000-2999	67	(29.1)
	≥3000	41	(17.8)
Frequency of sexual intercourse (times/week) (mean±SD= 2.6±0.89)	<Once a month	23	(10.0)
	1-2 times a month	74	(32.2)
	1-2 times a week	102	(44.3)
	3-4 times a week	26	(11.3)
	>4 times a week	5	(2.2)
Menopause	Yes	33	(14.3)
	No	197	(85.7)
Number of children (mean±SD= 3±2)	<2	92	(40.0)
	2-5	100	(43.5)
	>5	38	(16.5)
Husband's age (year) (mean± SD=42.7±11.3	<30	38	(16.5)
	30-39	62	(27.0)
	40-49	63	(27.4)
	≥50	67	(29.1)
Duration of marriage (year) (mean±SD= 15.5±1.3)	<14	124	(53.9)
	≥14	106	(46.1)

Table 2: Risk factors associated with women with genital arousal disorder

Potential risk factors	Variables		χ^2; *p*-value
	Normal (n = 114)	Genital arousal disorder (LVL) (n= 116)	
Age			
≤45 years old	92 (57.1%)	69 (42.9%)	12.3; <.001
>45 years old	22 (31.9%)	47 (68.1%)	
Race			
Malays	95 (54.3%)	80 (45.7%)	6.5; .01
Non Malays	19 (34.5%)	36 (65.5%)	
Salary (RM)			
<1,875	59 (51.3%)	56 (48.7%)	0.29; .60
≥1,875	55 (47.8%)	60 (52.2%)	
Duration of marriage			
Married <14 years	74 (59.7%)	50 (40.3%)	11.0; .001
Married ≥14 years	40 (37.7%)	66 (62.3%)	
Academic status			
Higher academic	94 (53.7%)	81 (46.3%)	5.04; .025
Lower academic	20 (36.4%)	35 (63.6%)	
Husband's age			
Age ≤42 years old	74 (60.2%)	49 (39.8%)	11.9; .001
Age >42 years or more	40 (37.4%)	67 (62.6%)	
Number of children			
≤3 children	78 (55.3%)	63 (44.7%)	4.25; .028
>3 children	36 (40.4%)	53 (59.6%)	
Sexual intercourse			
<3 per month	90 (45.2%)	109 (54.4%)	11.12; .001
≥3 per mo nth	24 (77.4%)	7 (22.6%)	
Medical problem			
Yes	15 (41.7%)	21 (58.3%)	1.00 ; .32
No	98 (50.8%)	95 (49.2%)	
Dysmenorrhea			
Yes	32 (49.2%)	33 (50.8%)	0.04; .95
No	82 (49.7%)	83 (50.3%)	
Menarchy			
Yes	81 (48.2%)	87 (51.8%)	0.46; .50
No	33 (53.2%)	29 (46.8%)	
Menopause			
Yes	8 (24.2%)	25 (75.8%)	9.9; .002
No	106 (53.8%)	91 (46.2%)	
Hormonal replacement therapy			
Yes	1 (33.3%)	2 (66.7%)	3.12; .6
No	112 (49.6%)	114 (50.4%)	

1-2 times a week) (χ^2=11.12, *p*=0.001), and those at post-menopausal state (χ^2=9.9, *p*=.002). There was no significant difference between these two groups in terms of salary (χ^2=1.12, *p*=.29), presence of medical problem/s (χ^2=1.0, *p* =.32), dysmenorrhea (χ^2=0.04, *p*=.95), age of menarche (χ^2=0.46, *p*=.5) and hormonal replacement therapy (χ^2=3.12, *p*=.6).

From Multiple Logistic Regression (MLR) analysis, only frequency of sexual intercourse was found to be significantly predictive of genital arousal disorder among these woman (*p*=.029). From the above model, frequency of sexual intercourse has the highest influence on lubrication (Wald =4.48). Lower frequencies of intercourse significantly reduce lubrication level, (OR=0.35, 95% CI: 0.13-0.90).

Discussion

The terminology of female genital sexual disorder is relatively very new in local Malaysian population and appear briefly only in the clinical context recently [13], even in the Western society [3,4]. Sexual excitement – both subjective and physiological can precede sexual desire [4,21]. Issues related to genital arousal disorder are traditionally considered to be too private to be disclosed and could only be shared with certain people like parents or traditional healers or confined between spouses in the bedroom: therefore neglected and remain untreated [13,14,22]. To complicate the matter, in the past, many researchers created their own definitions for sexual disorders, which inevitably led to confusing and incongruent results. An attempt to address this issue globally was made through a panel of experts at the Consensus Development Conference on FSD in 1998 [23]. With the introduction of academic sexology linked to medicine, discussion on female sexual disorder would become more acceptable in Malaysian society [14].

Research in the area of female sexual dysfunction are scanty and at infantile stage in Malaysia – and it is hoped that this piece of research work would enlighten academicians, politicians and health care policy makers in future planning for sex education and providing sex counseling to couples and women with sexual disorder. However, research in sexual difficulties was not given adequate attention compared to the male sexual function, as there was no apparent "cure" or current revolutionary pharmacotherapy in women than compare to male – and partly because sexual function in women are more complex and does not follow the linear male sexual response cycle [12,21]. Whipple (2002) highlighted the difficulties in studying women sexual function, in which so many non-anatomic and non-physiological factors play a role [21]. Male sexual dysfunction can be more objectively define and diagnosed, and interventions can be more objectively ranked regarding efficacy comparing to female sexual difficulties [24]. Furthermore, sexual activity frequency, a measure used for male sexual function, cannot be used as an accurate marker of female sexual function because women may still be able to remain sexually active with partner while experiencing sexual difficulties [25]. Female sexual function may also be more dynamic than a male sexual dysfunction. Although there are significant anatomic and embryologic parallels between men and women, the complex nature of female sexual dysfunction is clearly distinct from that of the male.

This research is an attempt to look on the gravity of genital sexual arousal disorder in women attending a primary care setting. The studied urban Malaysian population has relatively younger age with high level of educational background. They came from the lower middle socioeconomic group based on their monthly family income with a majority of them having been married for more than 10 years. Nearly half of them are very active sexually, with frequency of sexual intercourse 1–2 times/ week and more than half are from premenopausal group.

The prevalence of females with genital sexual arousal disorder was 50.4%. This figure is about 3 more times more common than the Western population [5]. This is also higher than that in another study [26]. This international survey [26] on 407 subjects found 19% of women and 11% of men reporting of not considering sex pleasurable. Of the women interviewed, 23% reported inadequate lubrication, with a significant increase of this complaint in women aged 50-65 years.

This high prevalence of women reporting genital arousal disorder may be explained by the fact that they were assessed privately using a rather simple questionnaire in a medical setting where anonymity was assured. In addition, helps could be offered if they needed it. This finding shows that despite the societal, cultural, and religious norms, the chance of Malaysian women to disclose their sexual discontentment is

high, given the right situation and the right way. The high prevalence of sexual difficulties only reported after a systematic assessment (rather than spontaneous reports to their doctors) also confirmed the finding of another study on female sexual difficulties in Asia, which found that nearly half of them did not seek treatment for the problems [12].

Increasing age as a factor to be associated with genital arousal disorder in this study is not surprising and has been found in other studies [26]. It is rather expected that sexual difficulties would be less reported among the Malay women, who are synonymously Muslims. The Malays are traditionally more inhibited when it comes to sex, as well as, Islam prohibits sexual disclosure except only for treatment purposes [13]. However, we are not sure specifically, why genital sexual arousal disorder affects more on the non-Malays (mainly Chinese and Indians). This finding needs further replication using a larger sample size. The non-Malays included in this study had to be able to speak the study languages (English and Malay). This ability reflects higher education levels and being more liberated, which may explain the spontaneity of reporting sexual difficulties.

We found that the potential risk factors that may impair genital sexual arousal in Malaysian women are old age, non-Malay, a lower academic status, married longer and older husband, having more children and having less sexual intercourse (less than 1–2 times a week). There were no significant findings in term of having any medical problems, but women at postmenopausal age were at risk. We have significantly more non-Malays reporting the lack of lubrication, probably due to cultural belief on sexual issues, despite of more Malays were recruited in this study. Having less sexual intercourse could be due to the complications of genital sexual arousal disorder as we could not determine the cause and effect in this study. The longer period of marriage would provide more chances of reporting sexual dysfunction. Women with genital sexual arousal disorder tend to have more children – probably the psychobiological aspect of parity has a significant effect on their sexual functioning, either due to hormonal changes, increase responsibility to take care of the family and due to lack of privacy for sexual encounters. The lower educational status would reflect their ignorance of sexual rights. Interestingly, in our study, salary income, medical problem or dysmenorrhea was not found to be associated with genital arousal disorder. However, serious medical and psychiatric disorders that could obviously impair sexual functioning had been excluded from the study [27-29].

Sexual desire and vaginal lubrication of a woman may be affected by hormonal changes that occur as a result of normal female physiology, such as menstrual cycle, postpartum states, lactation and menopause – or due to fatigue and decrease well-being [28] – or psychological and intimate relationship [1].

There are a few limitations of this research. First, relationship issues, e.g., marital satisfaction between couple, were not investigated in this study. Genital arousal disorder during sexual activity could actually be reflective of lack of intimacy and eroticism between couples [1]. Second, we did not look into the sexual functioning of the male spouses. Sexual difficulties in women may be associated with sexual dysfunction among their spouses, especially, erectile dysfunction [30]. However, we found that women with genital arousal disorder tend to have older husbands with possible medical problems. It is known that that medical problems among older men [12] could affect their sexual performance, and this may have indirectly contributed the women's sexual dysfunction [2,4].

In term of respondents, this study included only the married women with sexually functioning partners. Those who were not married (single, divorce or widow) were excluded from this study because most Malaysians were unable to accept the

extramarital sexual relationship. However, there were many unmarried women sexually were active [Sirat HH personal communication, February 10, 2005]. Those who were not married but sexually active were approached during the pilot stage but they were reluctant to participate due to religious and cultural reasons.

Another limitation is the language barrier that caused a significant number of the Chinese and Indians to be excluded from the study. With this limitation, the author would recommend the development of validated Female Sexual Function Index Questionnaire in various languages such as in Mandarin or Tamil in the future.

This research has an important impact to our current understanding of the magnitude of female sexual dysfunction in our primary care population. It indicates the need for treatment and services for sexual dysfunction in the clinical settings, which are tailored to the local needs of women population. Psychological and intimacy based approaches for sexual difficulties in women are very crucial in sex therapy [1,2,4,13]. Aside from hormone replacement therapy, medical management of female sexual dysfunction remains in experimental phases [2,4,32]. Nevertheless, it is crucial to understand that not all female sexual complaints are psychological, and that there are possible therapeutic options.

With the improvements of medical attention, female sexual difficulties have been recognized as an important element as in their male counterpart in terms of diagnosis [33,34] and right for treatment in a more widely accepted, and understood diseases. The importance of addressing issues of sexual difficulties in women has emerged recently with more interest to do research in this area, including using a validated questionnaire [17,18] for health planning purpose and improvement of quality of life.

The ideal approach to treat female sexual dysfunction, including genital sexual arousal disorder, is a collaborative effort between psychiatrists and physicians. These include a complete medical and psychosocial evaluation [1-4], as well as inclusion of the partner or spouse in the evaluation and treatment process [35].

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Benzodiazepine overuse in an internal medicine out-patient department: a prospective study

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Abstract
Objective: This study aims to assess benzodiazepine overuse, in particular indications, prolonged use, and dependence for usage in out-patients treated at the internal medicine clinic of Chiang Mai University Hospital. *Methods:* The indications of benzodiazepine usage were examined by using the Thai Hospital Anxiety and Depression Scale in patients who were started on benzodiazepines. The duration of benzodiazepine usage was classified into: i) less than 1 month; ii) 1-6 months; and iii) longer than 6 months, and benzodiazepine dependence was assessed by using the Severity of Dependence Scale. *Results:* Of 40 out-patients started on benzodiazepines, only one of them (2.5%) had clinically significant anxiety. Of 58 out-patients receiving benzodiazepines, 42 patients (72.4%) had used benzodiazepines longer than 6 months. In addition, 8 patients (13.8%) were dependent on benzodiazepines. *Conclusions:* Benzodiazepine overuse is common in physically ill out-patients, even in the university hospital. Almost half of the surveyed patients appear to have prolonged benzodiazepine use; however, only a few patients are dependent on benzodiazepines.

Key words: *benzodiazepine overuse, indication, duration, dependence*

Introduction

Benzodiazepines are among the most widely prescribed psychiatric drugs in the world [1]. They have been used not only in psychiatric patients but also in physically ill patients. Previous studies found that besides psychiatrists, neurologists and internists are the doctors who most frequently use benzodiazepines in their practices [1,2]. Although benzodiazepines are considered well tolerated, especially when compared with older drugs, their adverse side effects can cause a number of problems, such as sedation, motor incoordination, cognitive impairment and disinhibition [3,4]. Moreover, long term use of benzodiazepines may leads to dependence, tolerance and withdrawal [4,5].

There are greater concerns about benzodiazepine's side effects particularly in the elderly, in whom adverse events include falls from ataxia, which cause hip fractures, and confusion [4,6]. Although increasing awareness of benzodiazepine's side effects may decrease their overall usage [5,7,8], they are still frequently prescribed for a long period of time, especially in developing countries where there is no clearly recommended guideline.

As a drug class without definite indication,

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the rationales for the use of benzodiazepines have been controversial. In clinical practice, their main indications are treating anxiety and depression [1]. However, these drugs are commonly prescribed for a variety of somatic complaints which leads to the problem of overuse [9]. Srisurapanont and his colleagues carried out a study in the northern part of Thailand and reported that, for general practitioners, the most common use of benzodiazepines is for anxiety with insomnia (93%), followed by panic disorder (78%) and depression (43%). Some general practitioners also gave these medications for essential hypertension and low back pain. Moreover, 45% of them admitted that they had used benzodiazepines too much in the past year [10].

Regarding the duration of benzodiazepine treatment, some experts suggest that the efficacy of benzodiazepines for insomnia is decreased after 2 weeks, for anxiety after 4 weeks and for panic disorder after 12 weeks [9]. However, the appropriate duration for prescribing benzodiazepine is still an issue of debate. The UK data sheet for diazepam and temazepam recommends that benzodiazepines should be used only when the disorder is severe, disabling or causes marked distress [9]. Its use should be limited to short term (2-4 weeks), while extensions beyond this time require re-evaluation of the patient's status [8, 9]. In addition, the USFDA label of benzodiazepines states that the efficacy of these drugs at longer than 4 months has not been assessed by systematic studies [11]. However, a small number of studies have found that benzodiazepines are effective for a longer period (4-6 months) [12].

Benzodiazepine dependence is regularly seen. De Las Cuevas and colleagues found that 47% of patients using benzodiazepines for more than 1 month had benzodiazepines dependence [13]. According to the study of Uhlenhuth et al.(1998), benzodiazepine dependence could occur when doses within the clinical range were taken regularly over a 6-month period [14].

In several developed countries, various steps have been taken to control the prescription of benzodiazepines. Example strategies include disseminated documents on how to prescribe benzodiazepine (e.g., never prescribe on the first visit or to an unknown patient), advice about sleep hygiene, using sedative antidepressants or non-benzodiazepine sedatives instead of benzodiazepine, offering non-pharmacological supports or psychotherapy as the first choice [15,16], and reserving benzodiazepines for more severe cases of anxiety and insomnia. However, in developing countries, such as Thailand, there is still a limited concern about the side effects of benzodiazepines.

A study of benzodiazepine overuse, in particular at the internal medicine out-patient clinics, would increase the understanding of benzodiazepine use problems and may be a guide for the development of strategies to reduce benzodiazepine prescription. This study therefore aims to assess benzodiazepine overuse, mainly regarding indications, prolonged use and benzodiazepine dependence, in out-patients treated at an internal-medicine clinic of a university hospital.

Methods

This prospective study was carried out between March and April 2005 at Chiang Mai University Hospital, a tertiary general hospital in northern Thailand. Chiang Mai is the largest city in northern Thailand, with approximately 1,650,000 inhabitants in 2006.

The study evaluated out-patients receiving benzodiazepines from the hospital's internal medicine clinic. This study was approved by the Ethics Committee for Human Studies, Faculty of Medicine, Chiang Mai University.

Sample
This study included all patients at the internal medicine out-patient clinic. Participants were those who were at least 18 years old, received benzodiazepines, and gave written informed consent. No exclusion criterion was applied.

Instruments
The instruments used in this study were structured questionnaires to collect information in several areas. Those included:
i) demographic data for age, gender, marital status.
ii) drug use data for duration of benzodiazepine use, which were classified into:
- Short term (less than 1 month)
- Intermediate term (1-6 months)
- Long term (longer than 6 months).

iii) Thai Hospital Anxiety and Depression Scale (Thai-HADS) for assessing the existence of clinically significant anxiety or depression, which are major indications for benzodiazepines. The cut-off point indicating clinically significant anxiety or depression was 11 points or more. By the use of this cut-off point, the sensitivity and specificity of the Thai-HADS are 100.0% and 86.0% for anxiety, and 85.7% and 91.3% for depression, respectively [17]. This scale was used to examine patients that started using benzodiazepines during the study.
iv) Severity of Dependence Scale (SDS) for evaluating benzodiazepine dependence. The score of 7 points or more indicates a dependence on benzodiazepines. By the use of this cut-off point, the sensitivity and specificity of this measure are 97.9% and 94.2%, respectively [18].

Since benzodiazepine use is more concerned in elderly people, a subgroup analysis of data obtained from subjects aged 65 years or older was also performed.

Results
Of the 98 internal medicine out-patients receiving benzodiazepines, most were female (64.3%) and most were married (82.6%). Their mean age was 55.4 years (SD=15.3). Of 40 out-patients (40.8%) who started receiving benzodiazepines during the survey, only one of them (2.5%) had clinically significant anxiety. Most of the patients were given benzodiazepines for more than 6 months (72.4%). Only 20.7% and 6.9% received benzodiazepines for 1-6 months and less than 1 month respectively.

Overall, eight patients (13.8%) were dependent on benzodiazepines. Six and two of them received long- and medium-term treatment respectively. None of the subjects given short-term treatment had benzodiazepine dependence (see Table 1).

Thirty-five of the 98 subjects (35.7%) were 65 years old or older. The subgroup analysis found that, of the 15 elderly patients started on benzodiazepines, one of them (6.7%) had clinically significant anxiety. Fifteen patients (75.0%) received benzodiazepines for more than 6 months, and none in this subgroup received short-term treatment with benzodiazepines. Three elderly subjects (15%), who received long-term benzodiazepine treatment, were dependent on benzodiazepines.

Table 1: SDS score in patients receiving benzodiazepines

SDS score	**<1 month (n=4)**	**1-6 months (n=12)**	**>6 months (n=42)**	**Total (N=58)**
Less than 7	4 (100%)	10 (83.3%)	36 (85.7%)	50 (86.2%)
7 or more	0 (0%)	2 (16.7%)	6 (14.3%)	8 (13.8%)

SDS = the Severity of Dependence Scale

Discussion

Of the 40 patients who were started on benzodiazepines, only one of them had anxiety or depression, which indicates that 97.5% did not meet the major indications for the use of benzodiazepines. Based on indications and contraindications, a previous study found that benzodiazepines were prescribed inappropriately in 65% of those receiving them [19]. Although the indications and the results of previous and the present studies are relatively different, both studies found high prevalent rates of the off-label use of benzodiazepines.

Up to 72.4% of all patients received benzodiazepines for longer than 6 months, although past studies showed there was no evidence of efficacy. The percentage of long-term treatment found in this study is higher than previous studies, which were 15-37% [20, 21].

In this study, the point prevalence rate of benzodiazepine dependence is 13.8%, which is in the range of 3.3% and 97% obtained from previous studies [13, 22-25]. The wide range of the prevalence rate among these studies may cause by the population differences, criteria and measurements.

Elderly patients have higher rates of dependence and prolonged use compared to the whole studied population. These findings are similar to the previous study, which found that old people had a higher risk of prolonged use than the general population [21].

The strength of this study is the measures used for screening dependence and anxiety/depressive disorders. However, there are some limitations, including small sample size, assessing the duration of treatment by self-reporting, and using screening tests for anxiety/depression and dependence.

In conclusions, benzodiazepine overuse is common in physically ill out-patients, even in university hospitals. This problem should concern patients, clinicians and policy makers. Almost half of the patients in this study appeared to have prolonged benzodiazepine use. Alternative treatment, such as relaxation training and sleep hygiene education, should be publicized. Despite the overuse problem, few patients are dependent on benzodiazepines. As very few patients initiated with benzodiazepines have clinically significant anxiety or depression, further studies may be needed to examine the indications of benzodiazepines in this population.

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Conflict of interest

The authors declare that they have no conflict of interest.

Authors' Contributions

SS and MS conceived and initiated the study, conducted the survey and analyzed the data. PL conceived and initiated the study. All authors participated in the writing of successive drafts of the manuscript and all have read and approved the final manuscript.

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ORIGINAL ARTICLE

Fixed-dose schedule and symptom-triggered regimen for alcohol withdrawal: a before-after study

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Abstract
Objectives: To evaluate the efficacy, safety, benefits and cost of alcohol detoxification after switching from a fixed-dose schedule (FDS) to a symptom-triggered regimen (STR). *Methods:* This retrospective study was carried out in inpatients receiving alcohol detoxification. The data of alcohol dependent patients receiving STR during March – September 2006 were compared with those of patients treated with FDS between August 2005 and February 2006. *Results:* The mean age, alcohol use and history of delirium tremens were not significantly different between groups. The mean dosage of benzodiazepines in the STR group (91.3 mg equivalent to diazepam) was lower than that of FDS (465.3 mg equivalent to diazepam), (p<.001). The mean length of hospitalization was shorter in the STR group (10.6 vs. 16.8 days, p=.003). There was no significant difference in major complications. Oversedation was significantly less frequent in the STR group (p <.001). The treatment cost was significantly lower in the STR group (p<.05). *Conclusions:* Despite the limitations of the study design, STR is as effective as FDS with less frequent complications, shorter length of hospitalization and decreased cost of treatment.

Key words: *alcohol withdrawal, symptom-triggered regimen, fixed-dose regimen*

Introduction

Alcohol dependence is a major public health problem. It has been ranked as the fourth leading cause of disability and health care burden in a global report. In addition, it contributes to approximately 1.5% of all causes of death [1]. In respect to all types of alcoholic beverage and spirit consumed in 2005, Thai people were ranked as 40th and 5th respectively, in comparison to other countries [2]. Thus, alcohol-related costs adversely affect Thailand healthcare system and society at large.

Alcohol enhances gamma-aminobutyric acid's (GABA) inhibitory effects, leading to an increase in excitatory glutamate receptors. When alcohol is removed acutely, withdrawal symptoms occur. Withdrawal signs and symptoms are frequently minor but can develop into a severe, even fatal condition. Up to 71% of individuals presenting for alcohol detoxification manifested significant symptoms of alcohol withdrawal [3]. The common ones include tremors, craving for alcohol, insomnia, vivid dreams, anxiety, hypervigilance, agitation, irritability, loss of appetite, nausea, vomiting, headache, and sweating [4]. The most severe form of the withdrawal syndrome is alcohol withdrawal delirium, also known as delirium tremens

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(DTs). Untreated DTs has a 20% mortality rate [5]. The best treatment for DTs is prevention. Therefore, the patients with recognized alcohol withdrawal symptoms should be carefully monitored to prevent the development of alcohol withdrawal delirium [5]. Detoxification is the first step towards the treatment of alcohol dependent persons. Some patients, especially those with a history of alcohol withdrawal seizure or delirium, are likely to be admitted for inpatient detoxification.

In Maharaj Nakorn Chiang Mai Hospital, the number of inpatients receiving alcohol detoxification has increased enormously since 2004. In the psychiatric ward, the fixed-dose schedule (FDS) of benzodiazepines had been used prior to the implementation of symptom-triggered regimen (STR) of benzodiazepines in early 2006. Although FDS has been considered as a standard treatment for individuals withdrawing from alcohol, during 2004-2005, 56% of alcohol dependent inpatients receiving FDS at the psychiatric ward developed delirium within the first week of treatment. Not uncommon, patients receiving medication more than necessary results in drug-induced delirium, prolonged duration of treatment, and wastefulness of personnel [6]. Recent recommendations for treating alcohol withdrawal syndrome suggest a symptom-triggered approach based on frequent objective assessment of the patient [7,8].

STR, a personal adaptation of medication dosage, uses questionnaires that evaluate the occurrence and intensity of alcohol withdrawal. Instruments such as the revised Clinical Institute Withdrawal Assessment for Alcohol scale (CIWA-Ar) [9] and Alcohol Withdrawal Scale (AWS) [10] have been used. There are many studies determining the use of STR together with those objective scales. STR has been reported more effective than FDS by shortening the duration of hospitalization and benzodiazepine treatment [12-14]. Reoux and Miller [15] also demonstrated the decrease of hospitalization and benzodiazepine treatment by using STR in alcohol withdrawal patients in a general hospital. Rate of complication, including DTs, occurred less frequently in the symptom-triggered approach compared with the fixed-dose approach [8,16].

As mentioned above, the symptom-triggered regimen of benzodiazepines was proved to help reduced complications during the treatment of alcohol withdrawal. To our knowledge, there has been a little evidence in the application of this regimen in less developed countries, especially with respect to treatment cost. The purpose of this study was to compare the treatment efficacy, safety, benefits and cost of STR modified by our patient care team and the usual care (the FDS) in alcohol withdrawal patients. Our STR called Assessing and Benzodiazepine Dosing Regimen for Alcohol Withdrawal (ABDRAW) [See Appendix] was modified from an Australian Guideline [11].

Methods

Subjects

We retrospectively identified psychiatric inpatients receiving alcohol detoxification at our psychiatric ward between 1st August 2005 and 30th September 2006. The study was approved by the Ethics Committee for Research, Faculty of Medicine, Chiang Mai University.

The inclusion criteria were: i) aged of 20 years old or older, ii) meeting the DSM-IV-TR diagnostic criteria for alcohol dependence and iii) alcohol abstinence no longer than 7 days. Patients who initially presented with alcohol withdrawal delirium were excluded.

Identified patients were divided into two groups. The first one is the pre-implementation group (Aug. 2005 - Feb. 2006), who were treated with FDS. Patients in group two (Mar. - Sep. 2006) were

treated by the use of ABDRAW in which the Alcohol Withdrawal Scale [10] was used as a guide for benzodiazepine dosing.

Assessment

Age at admission, sex, alcohol use history, medical and psychiatric comorbidities and history of previous alcohol withdrawal complications were collected from the medical records of eligible patients. Outcomes of treatment were determined by the total benzodiazepine dosage equivalent to diazepam (in milligrams); current complication of alcohol withdrawal including seizure, delirium, oversedation; length of hospital stay; and cost of treatment.

Interventions

For FDS, the medical staff gave flexible doses of benzodiazepines at the best judgements. By applying the ABDRAW, physicians evaluated the severity of alcohol withdrawal symptoms, and the nurse followed through the protocol instructions. Benzodiazepine doses were guided by the AWS scores of the patient. If the patient had an AWS score of 5 or higher, he would receive the starting dose of diazepam, which was 5-10 mg (or 1-2 mg of lorazepam). One hour after taking each dosage, withdrawal symptoms were reevaluated, and additional benzodiazepines were administered as long as the AWS scores remained at 5 or higher. The monitoring of alcohol withdrawal severity was discontinued if the AWS scores were lower than 5 for 72 consecutive hours.

Statistical analysis

Descriptive analysis was used for alcohol use history and patients' characteristics. To evaluate the effect of treatment, mean differences were assessed by the use of student (unpaired) t-test, and Fisher's Exact test was used to compare categorical variables. Two-tailed, *p-values* less than .05 were considered as statistical significances.

Results

Characteristic of subjects

Forty-one consecutive patients were admitted into psychiatric ward for alcohol detoxification between August 2005 and September 2006. All subjects were men who had alcoholic beverages within 7 days prior to admission. Four of twenty (20.0%) patients receiving FDS and 3 of 21 (14.3%) patients given STR were excluded due to delirium upon admission. The numbers of subjects included in this analysis were 16 for the FDS group and 18 for the STR group.

There was no significant difference between groups with respect to age, marital status, and employment (see Table 1). In addition, alcohol consumption, duration of alcohol use and time since last drink and medical and psychiatric comorbidities were also similar. Previous episodes of alcohol withdrawal delirium were documented in 5 patients of the STR group (27.8%) but none in the FDS group (p=.18).

Benzodiazepine treatment

The total amount of benzodiazepines equivalent to diazepam were calculated. The STR group received a significantly smaller amount of benzodiazepines than the FDS group (91.31±107.09 mg vs. 465.34± 249.70 mg, p<.001) (see Table2). Duration of benzodiazepine treatment was also significantly shorter for the STR group.

Complications and adverse events

The incidence rates of oversedation and seclusion/restraint were significantly less frequent in the STR group (0 vs. 9 for oversedation, p<.001; 3 vs. 9 for seclusion/restraint, p=.03). Delirium was found in 2 and 4 patients receiving STR and FDS, respectively (p=.39). The occurrences of other complications and adverse events, including, seizure, aggressive behavior and falling, were not significantly different (see Table 2).

Length of stay and cost of treatment

Compared to the FDS group, the STR group had significantly shorter hospitaliza-

tion (10.6±3.5 days vs. 16.81±7.44 days, *p*=.003) and lower cost of treatment (6,515.17±2,432.66 Thai baht vs. 11,845.56±7,693.02 Thai baht, *p*=0.009) (see Table 3). The service and accommodation cost, but not the medication and investigation costs, was significantly lower in

Table 1: Demographic characteristics and alcohol use history

Characteristic	**Fixed-doses group (N=16)**	**Symptom-triggered group (N=18)**	***p*-value**
Age, yrs (mean± SD)	50.44 ± 7.37	46.11 ± 7.61	.10
Sex,%	Male, 100	Male, 100	
Current marital status			
Married	10	10	
Separated/divorced/widowed	5	5	
Single	1	3	
Currently employed	13	17	.32
Alcohol use history			
Alcohol consumption			
Duration of alcohol use, yrs.	22.81 ± 9.36	17.67 ± 8.35	.10
Time since last drink, days	1.61 ± 1.98	0.64 ± 1.37	.11
Previous withdrawal history			
Seizure	1	6	.09
Delirium	0	5	.18
Hallucinations	3	3	1.0
Comorbid psychiatric condition			
Depression	4	2	.39
Bipolar	3	1	.32
Others	0	2	.49
Comorbid medical condition			
GI (i.e. cirrhosis)	6	3	.25
CVS (i.e. hypertension)	0	2	.49
CNS (i.e. old CVA)	1	0	.47
Others	6	2	.11

Table 2: Comparison of treatment outcomes by treatment groups

Characteristic	**Fixed-doses group (N=16)**	**Symptom-triggered group (N=18)**	***p*-value**
Benzodiazepine treatment			
Total benzodiazepine dosage equivalent to diazepam (mg)	465.34 ± 249.70	91.31 ± 107.09	<.001
Complications			
No. of seizure	0	0	
No. of delirium	4	2	.39
No. of oversedation[a]	9	0	<.001
Adverse events			
Aggressive	1	1	1.0
Falling	1	0	.48
Seclusion or restrained	9	3	.03

[a]Oversedation was defined as sleepiness or drowsiness and instability, and those resulted in disruption of the sleep-wake cycle, impairment in daily functioning, diminished ability to attend therapeutic activities, and discomfort.

Table 3: Comparison of the hospitalization and cost of treatment between groups

	Fixed-doses group (N=16)	**Symptom-triggered group (N=18)**	***p*-value**
Length of hospital stay, days	16.81 ± 7.44	10.61 ± 3.47	.003
Type of Cost (Thai Baht)			
Medication	1,246.69 ± 2,340.07	975.11 ± 867.84	.67
Lab & X-ray	1,734.37 ± 1,374.49	1,076.68 ± 777.20	.10
Service & accommodation	8,677 ± 4,904.67	4,413.39 ± 1736.06	.004
Total	11,845.56 ± 7693.02	6,515.17 ± 2432.66	.009

the STR group (p=.004). Because the service and accommodation was the main part of the total cost of treatment, the total cost of treatment in the STR group was, therefore, significantly lower (p =.009).

Discussion

Despite of the lower dose of benzodiazepines, STR is at least as effective as FDS for alcohol detoxification. In comparison to the alcohol dependent patients receiving FDS, those given STR are less likely to have oversedation and seclusions/restraints. In addition, STR also leads to a shorter duration of hospitalization and a lower cost of treatment.

The results of this study are in consistence with previous trials in western countries [12,13], and in Thailand [14,17]. All studies show that STR is as effective as FDS but superior to FDS in respect to lower doses of benzodiazepine, fewer complications and shorter hospitalizations. There has been very little evidence on the cost savings of treatment, and this study shows, even in treatment settings with fewer resources, STR is also helpful in reducing the cost of inpatient alcohol detoxification.

Despite the obvious evidence, the nursing staff involved in this study preferred to have an objective scale to guide their medication dosing. The nurses, who previously used CIWA-Ar, mentioned that the AWS is more practical and less complicated than the former. Suspiciously, a few subjects experienced delirium tremens after discontinued monitoring withdrawal symptom. This was probably due to an abrupt discontinuation of benzodiazepines at the time of hospitalization. So it was important to realize that withdrawal scales are not diagnostic instruments, and the withdrawal score on its own may not be enough to indicate progression to a more serious form of withdrawal. Clinicians should not rely on withdrawal scale scores alone to monitor withdrawal, but must also use their clinical judgements and other observations.

Although these findings may have certain applicability in managing alcohol withdrawal patients, it is important to recognize some limitations in the generalisability. First, all subjects were in a psychiatric unit, where medical comorbidities occurred less frequently. Therefore, it may not hold true for other settings, such as general medical ill patients. However, this study did not exclude patients having other medical conditions. Second, there is potential weakness with this study inherent in a retrospective study design. The defect of the data collection system was discovered. We identified patients through discharge diagnosis and verified those by reviewing their records during admission. Third, in contrast with other studies, which used the CIWA-Ar for evaluating the occurrence and intensity of alcohol withdrawal [7-8, 12-17], this study used the AWS. Forth, while we made an effort to account for variables that would affect outcomes, other possible confounders were the exact nature of alcohol withdrawal symptoms, especially insomnia, might have an impact on a higher dose of diazepam even though the AWS score is lower than 5. Other limita-

tions of this study included a small sample size, no assessment training for nursing staff and relying solely on the subjects' estimation and recollection of alcohol use history. Further studies should be conducted in a larger numbers of patients and staff who are well trained to use the regimen.

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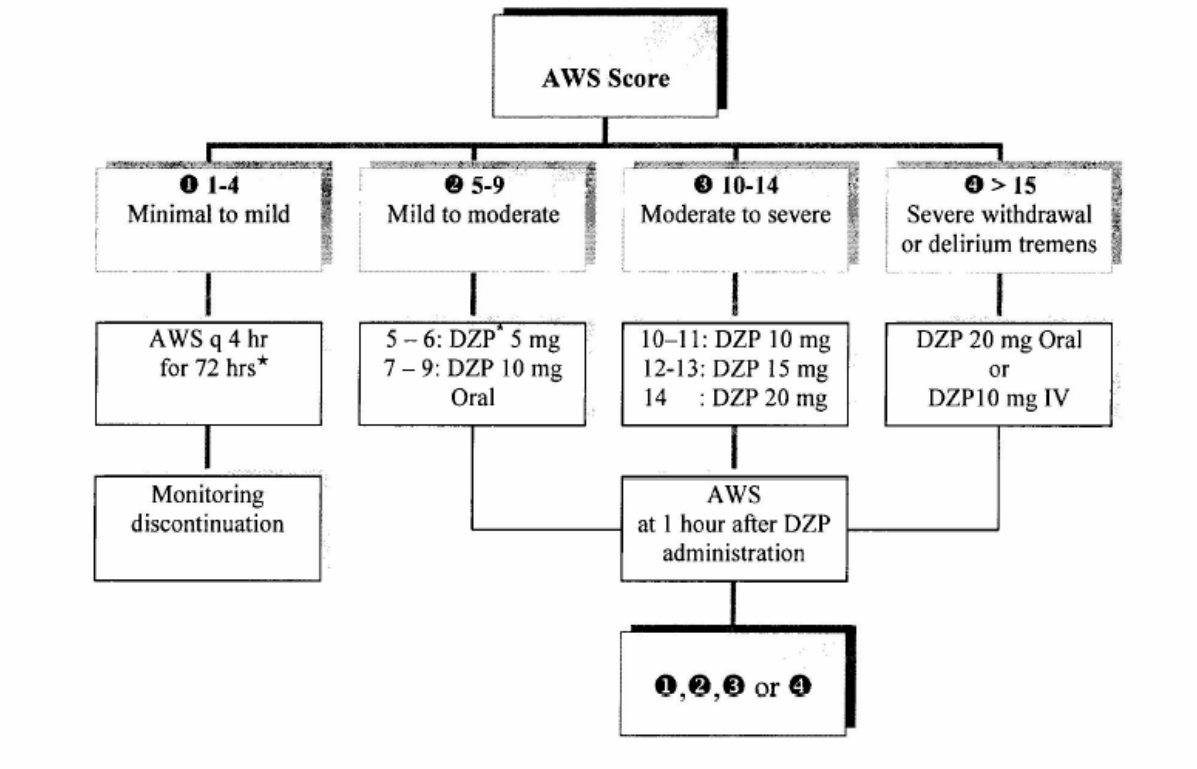
Appendix

Assessing and Benzodiazepine Dosing Regimen for Alcohol Withdrawal **(ABDRAW)**



*DZP= Diazepam

Note

- Physician's decision is also based on other conditions of the patients and resources available at the point of time.
- Physician should start at ❷ if the patient has a AWS score less than 5 but has a history of alcohol withdrawal seizure or delirium
- Physician should administer lorazepam 1 mg equivalent to Diazepam 5 mg for elderly patients and those who have severe hepatic diseases.
- Physician has to reevaluates the patient's condition and the dosing regimen every 24-48 hrs.
- Nurse has to notify physician if
    - The patient is in stuporous condition.
    - The patient has a respiratory rate of 14/minute or less
    - The patient received a total dosage of 80 mg diazepam (or equivalent) or more within 8 hrs
    - The patient has severe withdrawal (AWS score of 15 or more) or delirium for 4 consecutive hours
    - The patient has moderate to severe withdrawal (AWS score of 10-14) for 6 consecutive hours

Modified from:

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ORIGINAL ARTICLE

Cost analysis of treatment for schizophrenic patients in social security scheme, Thailand

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Abstract
Objective: To determine the cost of treatment for schizophrenic patients in Social Security scheme, Thailand. *Methods:* The paper reviewed available evidence in Thailand on the cost of schizophrenia treatment in different hospital settings and data of health service utilization obtained from various sources. The sensitivity analysis of direct health care cost of schizophrenia was conducted in social security system, both in outpatient and inpatient services. The cost for schizophrenia coverage per individual social security applicant was estimated in different contexts. *Results:* The total cost of treatment depends on the service utilization rate and unit cost of treatment. The annual direct health care cost of schizophrenic outpatients in Thai social security scheme was averagely estimated at about 171 million Baht. (Range: 28.5 million to 372 million Baht in sensitivity analysis). The annual direct health care cost of schizophrenic inpatients in Thai social security scheme was averagely estimated about 265.3 million Baht (Range; 22.7 million to 531 million Baht in sensitivity analysis). Aggregation the outpatient and inpatient treatment for schizophrenic employees accounted for 436.5 million Baht/year (Range from 436.5 million to 903 million Baht). The cost for schizophrenia coverage per individual social security applicant was about 48 Baht/year. (Range 5.63 Baht to 99.22 Baht). *Conclusion:* This study illustrated the cost of schizophrenia treatment in Thai social security scheme in various contexts, which might be useful in planning, preparing, budgeting and decision making. However, the huge societal impacts of schizophrenia should be carefully considered for policy makers.

Key words: *schizophrenia, social security scheme, Thailand, cost of treatment*

Introduction

As identified in the social security scheme, Thailand has had the full-fledged social security system under which the employees will be protected in term of accident, illness, disability and death, either related or unrelated to work performance [1]. However, in the "social security against illness", the important category in social security system, presented the coverage of social security fund including physical illnesses mostly. Except acute psychosis (last for 15 days or less, the Social Security Office excludes all other psychoses from the social security benefit. This leads to inequity in receiving proper compensations and services. Psychoses not only cause stigma but also contribute to the misunderstanding of differentiation between "psychoses" and "other psychiatric illnesses". Some employees with psychiatric disorders are, therefore, not be able to receive their treat

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ment benefits. Efforts to push for full realization of mental problems in social security system have been made continuously through the Psychiatric Committee in order to increase the opportunities of access to treatment for psychiatric problems. In our opinion, the major problem that is worth coverage due to its huge impact to society unless proper treatment is schizophrenia.

In order to reach the decision making, one of their concerns is how much to pay for the addition of schizophrenia into the illness coverage. Although cost analysis studies for schizophrenia treatment in Thailand, both outpatient and inpatient setting, have been performed previously, in this study, we would like to focus on schizophrenic patients in social security scheme specifically.

Method

We gathered the data from prior cost analysis studies concerning mental illnesses in Thailand.

Information of schizophrenic patient in social security system (see Table 1)

The data were gathered from:

- The number of social security members.

The most recent data from Social Security Registry in July 2007 included compulsory subscribed employees (8,735,863 persons) and voluntary subscribed employees (363,681 persons), for a total of 9,099,544 persons [2].

- Morbidity rate of schizophrenia in Thai population. The data were taken from the national survey in Thai population, 2001 [3], under the basic assumption that there is no significant changes of schizophrenic morbidity rate between years.
- Health services utilization ratio in Thai patients. Health services utilization ratio in Thai patients both in outpatient department (OPD) and inpatient department (IPD) services, estimated by expert focus group and from the social security office report. [4]

Data of unit cost in IPD and OPD treatment for schizophrenia

Cost analysis studies of schizophrenia treatment from two main institutes, Ramathibodi hospital studied in 2000 [5] and the Department of Mental Health, Ministry of Public Health studied in 2005 [6] were reviewed and represented as unit cost in medical school hospitals and general hospitals. The unit cost consisted of the direct health care cost and indirect health care cost that were adjusted to the value in calendar year 2007, using consumer index price, the Bureau of Trade and Economic Indices, Ministry of Commerce, Thailand [7]. Details are shown in Table 2.

Table 1: General data*

Number of social security members	9,099,544
Morbidity rate of schizophrenia in Thai population	0.17%
Number of estimated schizophrenia in social security scheme	15,470
Mental health service utilization for schizophrenia	
i) OPD	
- Estimated by focus group of experts	4 visits/man/year
- Data from social security office	2.58 visits/man/year
ii) IPD	
- Estimated by focus group of experts	1 admission/man/year
-Data from social security office	0.047 admission/man/year

*Excluding those of members who did not access to mental health service utilization.

Table 2: Unit cost of schizophrenia treatment

Sources of cost	OPD (cost/visit)		IPD (cost/admission)	
	Cost in year of study	*Cost in 2007**	*Cost in year of study*	*Cost in 2007**
Unit cost of schizophrenia (Ramathibodi study,2000) (Baht)	5,019 (942-9,088)	6,010.41	28,660	34,321.23
Unit cost of Schizophrenia (Study of Department of Mental Health, Ministry of Public Health,2005) (Baht)	662	714.81	28,902	31,207.73

* Adjusted by consumer index price, Bureau of Trade and Economic indices, Minister of Commerce, Thailand

Table 3: Estimated direct health care cost of schizophrenia, outpatient department (OPD), in Thai social security scheme.

Number of schizophrenia in social security member[a]	Mental health service utilization[b]	Unit cost [c] (Baht/visit)	Total cost (a*b*c) (Baht/year)
15,470	Maximum utilization 4 visits/man/year (expert group estimation)	Ramathibodi study 6,010.41	371,924,170.80
		Dep. Mental Health study 714.81	44,232,442.80
	Minimum utilization 2.58 visits/man/year (Social Security Office data)	Ramathibodi study 6,010.41	239,891,090.17
		Dep. Mental Health study 714.81	28,529,925.61

Table 4: Estimated direct health care cost of schizophrenia, inpatient department (IPD), in Thai social security scheme.

Number of schizophrenia in social security applicants [a]	Mental health service utilization [b]	Unit cost [c] (Baht/visit)	Total cost [(a*b*c)] (Baht/year)
15,470	Maximum utilization 1 admission/man/year (expert group estimation)	Ramathibodi study 34,321.23	530,949,428.10
		Dep. Mental Health study 31,207.73	482,783,583.10
	Minimum utilization 0.047 admission/man/year (Social security office data)	Ramathibodi study 34,321.23	24,954,623.12
		Dep. Mental Health study 31,207.73	22,690,828.41

Assuming mental health services are assessable, schizophrenic patients in social security scheme have probability to use both outpatient and inpatient services in a year with expected utilization rates. We performed the sensitivity analysis of total cost to pay in a year for schizophrenia treatment in OPD and IPD. The lowest and highest total costs were presented by applying various contexts, in term of service utilization rate and unit cost of treatment. Also, average cost per 1 social security

Table 5: The annual cost and cost per applicant for schizophrenia treatment in Social Security Scheme**.**

Schizophrenia in Social Security Scheme	OPD cost	IPD cost	Total cost (OPD + IPD)
Cost for all applicants (Baht)			
Max	371,924,170.80	530,949,428.10	902,873,598.90
Min	28,529,925.61	22,690,828.41	5,1220,754.01
Average	171,144,407.34	265,344,615.68	436,489,023.02
Cost per one applicant (Baht)			
Max	40.87	58.35	99.22
Min	3.14	2.49	5.63
Average	18.81	29.16	47.97

Number of all social security applicants = 9,099,544

employee was calculated to illustrate the incremental cost if schizophrenia coverage is feasible.

Results

Estimated number of schizophrenic patients in social security member in 2007 is about 15,470 persons. Table 3 presents the total cost of OPD treatment for all schizophrenic patients in the social security scheme using various service utilization rate and unit costs of treatment. The outcome reveals the OPD treatment costs per year from highest to lowest cost. If all patients have the largest number of OPD visits and the highest OPD cost, the total cost per year will be approximately 371,924,170.80 Baht. If the patients have the largest number of OPD visits with the lowest OPD cost, the total cost per year will be 44,232,442.80 Baht. For the smallest number of OPD visits with the highest OPD cost, the total cost per year will be 239,891,090.17 Baht. Alternatively, for the smallest number of OPD visits with the lowest OPD cost, the total cost per year will be 28,529,925.61 Baht.

Table 4 shows the total cost of IPD treatment for all schizophrenic patients in the social security scheme using various admission rates and unit costs of IPD treatment. Similar to the outcomes of OPD settings, the total cost depends on the estimated number of IPD admissions in a year and the cost of IPD treatment. Therefore, the total IPD cost of schizophrenic treatment is between 22,093,855.74 Baht/year as the minimum cost and 516,780,687.49 Baht/ year as the maximum cost.

In Table 5, we present the expected total OPD and IPD costs of schizophrenia treatment to be covered in the social security system. The maximum, minimum and average costs are illustrated. The highest, the lowest and the average incremental costs per social security applicant are 99.22, 5.63 and 47.97 Baht/year, respectively.

Discussion

The sensitivity analysis has illustrated the significant difference of treatment cost for schizophrenia patients in the social security scheme. The wide range of results provides the fact in our mental health services. The total cost of treatment depends on the databases used for the analysis. The main variables influencing the outcomes are service utilization rate and unit cost of treatment. Concerning the service utilization rate, a marked difference is presented in the IPD service admission rate. Data from the expert group (psychiatrists) is much higher than the data obtained from the social security office (1 admission and

0.047 admission a year). Most psychiatrists in the focus group work in medical schools, which are tertiary care settings, so it is possible that most patients are severe cases that need more frequent admissions than ill employees, the target group of social security office.

Accord to the unit cost of IPD and OPD treatment settings, there are some differences between two institutes representative of medical school hospitals and general hospitals. Much higher labor cost and medication cost make the unit cost of OPD service in medical school hospitals markedly different from that in general hospitals. In this study, we use the minimum and maximum utilization rates and unit costs in order to perform the sensitivity analysis. This information may respond to the question of addition payment needed to include schizophrenia in the social security coverage. Various contexts in this study may be useful in planning, preparing and decision making if application is established in various conditions.

Some may suspect the benefits of adding schizophrenia into the social security coverage because their functional impairment may stigmatize them as the one who cannot employ or earn at all. Actually, schizophrenia has a wide range of severity and prognosis [8]. Some of them can work, earn and live independently, in particular, those receiving effective treatment and being adherent to treatment. Non-adherence to treatment, either due to the financial problems or poor compliance, is the most important factor in determining long term prognosis and burden to society [9]. Unsuccessful treatment of schizophrenic patient leads to a high hospitalization rate [10], failure in education, unemployment, lost earning, disability, suffering, violence, crime and premature death from suicide and homicide. These are enormous consequences to our society.

Beyond the health care cost, the economic consequences to society are categorized into direct non-health care cost (e.g., informal care cost, criminal cost: prison, police, justice) and indirect cost (productivity, lost due to unemployment, patients' or carers' absence from work, premature mortality) [11]. Many studies in various countries, such as UK, USA and Canada, have analyzed the monetary impact of schizophrenia. The findings in England in 2007 show that the direct cost of treatment is about 2 billion pounds but the burden of indirect cost and non health care cost to the society are huge with the amount of 4.7 billion pounds [12]. In 2002, the overall cost of schizophrenia in the US was approximately 62.7 billion US dollars in which 22.7 billion US dollars exceed the direct health care cost. The direct non health care excess cost estimated to be 7.6 billion US dollars, and the indirect excess costs were estimated to be 32.4 billion US dollars [13]. The analysis of the economic burden of Canada in 2004 found the direct health care cost and non-health care cost of 2.2 billion CAN dollars, the indirect cost from unemployment and mortality loss of 4.83 billion CAN dollars, which led to the estimated total cost of 6.85 billion CAN dollars [14]. These data show that the largest component of the total cost (about 70%) is the productivity losses associated with schizophrenia.

Not only schizophrenia, but other mental illnesses also provide a similar pattern that that the indirect cost is higher than the direct health care cost [15-17]. Indirect cost and direct non-health care cost would increase if the treatment is not effective. Even the large part of direct health care cost (hospital cost or IPD cost) would also increase in treatment failure. [18,19] Therefore, in societal view of economic evaluation, we can conclude that non-treatment (or ineffective treatment) option is more costly than the effective treatment. The most effective way to reduce the overall

societal cost is to develop effective and well accepted treatment [20].

In conclusions, these several lines of evidence support the idea of including schizophrenia into the social security coverage in order to prevent societal impacts and to reduce the large amount of indirect cost. At present, schizophrenic employees receiving no benefit from the social security fund have a higher risk for nonadherence to treatment. They are also at risk to be chronic schizophrenia with poor prognosis and being a big burden to society unless receiving health supports. Policy makers need to recognize the width of invisibly economic impacts beyond the out of pocket health care cost.

Conflict of interest: none.

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ORIGINAL ARTICLE

Consultation-liaison psychiatry in Maharaj Nakorn Chiang Mai Hospital

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Abstract

Objective: The aim of this study was to evaluate common problems in consultation-liaison psychiatry, characteristics of consulted patients, and medical and psychiatric diagnoses of the patients in Maharaj Nakorn Chiang Mai Hospital**.** *Methods:* We performed a retrospective descriptive study from June 2005 to August 2006. All participants were medically ill inpatients who consulted for psychiatric problems. The authors reviewed the demographic data such as age, sex, ward, systemic disease, medical disease, psychiatric provisional diagnosis and psychiatric diagnosis. *Results:* Four hundreds patients were consulted for psychiatric evaluation, 0.82 % of all general hospital inpatients, 235 (58.8 %) males and 165 (41.2 %) females. The modal age group was between 20 - 49 years old (58.8 %) mostly referred by the department of internal medicine and surgery. At discharge, common diagnoses were adjustment disorder (35.0 %), delirium (32.5 %), substance-related disorders (17.0 %), depressive disorders (13.3 %), and psychotic disorders (4.3 %). Sensitivity rates for diagnosis of these psychiatric disorders were 12.1%, 50.8%, 75 %, 43.4% and 64.7% respectively. *Conclusion:* Patients with high suicidal risk, in particular adjustment and depressive disorders are common in consultation-liaison psychiatry. Attention should also be given to patients with high risks of aggression, disruption, or disorganization, such as delirium, substance abuse, and psychotic disorders.

Key words: *consultation, medically ill patients, adjustment disorder*

Introduction

Consultation-liaison psychiatry deals with patients who have both psychological and physical symptoms under the care of other medical specialties. Psychiatrists have to identify mental disorder, diagnose, as well as work with the medical team for treatment plan. In western countries, the branch of consultation-liaison psychiatry is well established. There are also many studies in this area. Patients with medical illness such as disease of nervous system, endocrine disorder, delirium and substance use disorders may have co-morbidity of psychiatric problems. Moreover, patients with chronic medical illness may have many problems in coping with their health and present with anxiety, depression or suicidal ideation.

In developing countries, consultation-liaison psychiatry is a new branch of psychiatry**.** Only few psychiatrists are available in most general hospitals. From this point of view, we would like to survey the patterns of consultation-liaison psychiatry in our setting. The results will be analyzed and used to improve our services, as well as shaping the resident training program in the

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future.

Methods

The psychiatric consultation-liaison service is provided by the Department of Psychiatry, Faculty of Medicine, Chiang Mai University. Maharaj Nakorn Chiang Mai Hospital is a 1,800-bed university hospital in the Northern part of Thailand. When a patient is referred, interviews and consultations will be done on-site by staff psychiatrists and 3rd year psychiatric residents. Referrals for psychiatric consultation require a physician's order for such a request, specifying the reason for the consultation.

A retrospective review of psychiatric consultation reports completed by the residents during a 15-month period between June, 2005 and August, 2006 was undertaken. Copies of consultation reports kept on file were abstracted and coded for data analysis.

Extracted data included demographic data and medical/psychiatric diagnoses given at the times of consultation. Chi-square analyses and Pearson's correlation tests were performed to determine the significant differences. Defining all of the patients referred to the psychiatric consultation service as the population, accuracy, sensitivity and specificity rates were also calculated.

Results

Forty-nine thousands and one patients were admitted to the hospital during the study period. Four hundred patients were consulted for psychiatric assessment (0.82 %). Their demographic data are shown in Tables 1-3.

There was no significant different between consulted and nonconsulted groups in most diagnosed systems. The proportions of patients with reproductive/genitourinary disorders and dermatological disorders were significantly lower in consulted group. (p=.00 and .03, respectively).

There is no significant different between groups in many disease diagnoses except drug overdose, burns, trauma and degenerative disease (p=.005, .012, .003, and .013, respectively).

Provisional and final diagnosis

Common final diagnoses were adjustment disorder (n=140, 35.0%), delirium (n=130, 32.5%), substance-related disorders (n=68, 17.0%), depressive disorders (n=53, 13.3%), and psychotic disorders (n=17, 4.3%).

Table 1: Demographic data

Characteristics	Male	Female	Total
Sex [n (%)]	235 (58.8%)	165 (41.2%)	400 (100.0%)
Mean age [mean ± SD]	44.5±17.0	38.5±19.0	42.0±18.1
Ward			
Medicine [n (%)]	103 (25.8%)	82 (20.5%)	185 (46.3%)
Surgery [n (%)]	71 (17.7%)	33 (8.2%)	104 (25.9%)
Orthopedics [n (%)]	37 (9.2%)	16 (4.0%)	53 (13.2%)
Rehabilitation [n (%)]	11 (2.8%)	4 (1.0%)	15 (3.8%)
ENT [n (%)]	8 (2.0%)	6 (1.5%)	14 (3.5%)
Eye [n (%)]	2 (0.5%)	0 (0.0%)	2 (0.5%)
Pedriatric [n (%)]	3 (0.8%)	10 (2.5%)	13 (3.3%)
OB-Gyn [n (%)]	0 (0.0%)	14 (3.5%)	14 (3.5%)
Total [n (%)]	235 (58.8%)	165 (41.2%)	400 (100.0%)

Table 2: Systemic diagnosis

Systemic diagnosis	Male	Female	Total	p
Neurological system [n (%)]	49 (12.2%)	37 (9.2%)	86 (21.4%)	.725
Endocrinological system [n (%)]	4 (1.0%)	6 (1.5%)	10 (2.5%)	.330
Musculoskeletal system [n (%)]	42 (10.4%)	23 (5.7%)	65 (16.1%)	.284
Immunological system [n (%)]	7 (1.8%)	4 (1.0%)	11 (2.8%)	1.000
Cardiovascular system [n (%)]	11 (2.8%)	3 (0.8%)	14 (3.6%)	.169
Respiratory system [n (%)]	19 (4.8%)	6 (1.5%)	25 (6.3%)	.092
Gastrointestinal system [n (%)]	47 (11.7%)	31 (7.7%)	78 (19.4%)	.745
Rhematological system [n (%)]	1 (0.3%)	2 (0.5%)	3 (0.8%)	.572
Reproductive/genitourinary system [n (%)]	2 (0.5%)	16 (4.0%)	18 (4.5%)	.000*
Dermatological system [n (%)]	10 (2.5%)	1 (0.3%)	11 (2.8%)	.030*
Hematological system [n (%)]	7 (1.8%)	7 (1.8%)	14 (2.6%)	.585
Others [n (%)]	32 (8.0%)	27 (6.7%)	59 (14.7%)	.458
Multi-system involvement [n (%)]	4 (1.0%)	2 (0.5%)	6 (1.5%)	1.000
Total [n (%)]	235 (58.8%)	165 (41.2%)	400 (100.0%)	

* indicates significant difference between male and female groups

Table 3: Medical diagnoses in 400 consulted patients.

Disease diagnosis	Male	Female	Total	*p*
Drug overdose/toxic substance ingestion [n (%)]	30 (7.5%)	39 (9.8%)	69 (17.3%)	.005*
Alteration of consciousness [n(%)]	6 (1.5%)	1 (0.3%)	7 (1.8%)	.247
Infection [n (%)]	36 (9.0%)	15 (3.7%)	51 (12.7%)	.069
Malignancy [n (%)]	38 (9.5%)	34 (8.5%)	72 (18.0%)	.269
Burns [n (%)]	9 (2.2%)	0 (0.0%)	9 (2.2%)	.012*
Trauma [n (%)]	52 (13.0%)	18 (4.5%)	70 (17.5%)	.003*
Seizures [n (%)]	10 (2.6%)	12 (2.9%)	22 (5.5%)	.265
Stroke [n (%)]	23 (5.7%)	8 (2.0%)	31 (7.7%)	.087
Metabolic [n (%)]	7 (1.8%)	6 (1.5%)	13 (3.3%)	.779
Degenerative disease [n (%)]	7 (1.8%)	15 (3.7%)	22 (5.5%)	.013*
Other [n (%)]	14 (3.5%)	16 (4.0%)	30 (7.5%)	.181
Multiple diagnoses [n (%)]	3 (0.7%)	1 (0.3%)	4 (1.0%)	.646
Total [n (%)]	235 (58.8%)	165 (41.2%)	400 (100.0%)	

* indicates significant difference between male and female groups

Adjustment disorder

- Accuracy rates, sensitivity and specificity

Among 20 consulted patients with provisional diagnosis of adjustment disorder, only 17 patients (85%) were finally diagnosed with adjustment disorder. On the other hand, the 123 consulted patients (32.4%) with other provisional diagnoses were diagnosed with adjustment disorder finally. The sensitivity rate for a diagnosis of adjustment was 12.1% (male=7.4%, female=16.7%). The specificity rate for this diagnosis was 98.8% (male=100% and female=96.8%).

- Age group and sex difference

There was no significant difference among age groups (χ^2=9.793, df=7, p=.201). Peak ages of adjustment disorder in male and female patients were 40-49 and 20-29 years old, respectively (table 4). Significantly more females (43.6%, 72/165) than males (28.9%, 68/235) were finally diagnosed

Table 4: Common psychiatric disorders in consulted male and female patients classified by age groups.

Age group	Adjustment disorder		Delirium		Substance-related disorders		Depressive disorder		Psychotic disorder	
	male	*female*	*male*	*female*	*male*	*female*	*male*	*female*	*male*	*female*
< 19	8	11	1	0	0	0	1	5	0	0
20-29	11	21*	7	8	4	2	8	9*	2	2
30-39	14	9	18	6	18	0	11*	1	2	3*
40-49	15*	12	21*	9*	26*	2	3	1	4*	1
50-59	9	11	14	6	11	1	4	3	1	0
60-69	6	5	14	5	2	1	1	1	1	0
70-79	4	2	10	4	0	0	1	3	1	0
> 80	1	1	4	3	1	0	1	0	0	0
Total	68	72	89	41	62	6	30	23	11	6

* Peak ages of common psychiatric disorders in male and female patients

with adjustment disorder (χ^2=9.208, df=1, p=.002).

- Associated medical conditions

The patients with adjustment disorder mainly had drug overdose or corrosive ingestion (n=47/140, 33.6%), cancer (n=34/140, 24.3%) and trauma (n=17/140, 12.1%). Other medical conditions included infection (especially, HIV infection), degenerative disease, stroke, burns and seizures. There was a correlation between adjustment disorder and drug overdose/ corrosive ingestion (r=.310, p<.001).

Delirium

- Accuracy rates, sensitivity and specificity

Among 67 consulted patients with provisional diagnoses of delirium, 66 patients (98.5%) were finally diagnosed with delirium. On the other hand, 64 consulted patients (19.2%) with final diagnosis of delirium had previously provisional diagnoses of other psychiatric conditions (false negative). Only one consulted patient (1.5%) with a provisional diagnosis of delirium was finally diagnosed with another psychiatric disorder (false positive). The sensitivity rate of diagnosis in delirious patients was 50.8% (male=58.4%, female=34.1%). However the specificity was 99.6% (male=100%, female=99.2%).

- Age group and sex difference

There was a significant difference among age groups (χ^2=39.933, df=7, p<.001). The peak age of delirium in both males and females was 40-49 years old (see Table 4). Significantly more males (37.9%, 89/235) than females (24.8%, 41/165) were ultimately diagnosed with delirium (χ^2=7.495, df=1, p=.006).

- Associated medical conditions

Primary physicians could diagnose 50.8% of delirium correctly. Other reasons for referral for assessment were psychotic disorders (23.1%, 30/130) and substance use disorders (16.2%, 21/130). Patients with delirium mainly had substance use disorders (21.5%, 28/130) trauma (20.8%, 27/130), cancer (17.7%, 23/130), infection (17.7%, 23/130) and stroke (14.6%, n=19/130). Other medical conditions were degenerative disease, burns and seizures.

Substance-related disorders

- Accuracy rates, sensitivity and specificity

Among the 53 consulted patients with provisional diagnoses of substance-related disorders, 51 patients (96.2%) were diagnosed correctly. On the other hand, 17

consulted patients (4.9%) with a final diagnosis of substance-related disorders had previously provisional diagnoses of other psychiatric conditions (false negative). However, the two consulted patients (3.8%) with a provisional diagnosis of substance-related disorders were ultimately diagnosed with other psychiatric disorders (false positive). The sensitivity rate for these patients was 75% (male=74.2%, female=83.3%), while the specificity was 99.4% (male=99.4%, female=99.4%).

- Age group and sex difference

There was a significant difference among age groups (χ^2=42.398, df=7, p<.001). The peak age of substance-related disorders in males was 40-49 years old, while there was no peak age difference in female (see Table 4). Significantly more males (26.4%, 62/235) than females (3.6%, 6/165) were finally diagnosed with substance-related disorders (χ^2= 35.547, df=1, p<.001).

- Associated medical conditions

We found that 41.2% of patients (28/68) with substance-related disorders also had delirium together. Patients with substance-related disorders mainly had trauma (27.9%, 19/68), infection (17.6%, 12/68), seizures (11.8%, 8/68) and stroke (11.8%, 8/68). Other medical conditions were cancer, drug overdose, and metabolic disturbance.

Depressive disorders

- Accuracy rates, sensitivity and specificity

Among 91 consulted patients with a provisional diagnosis of depressive disorders, only 23 patients (25.3%) were finally diagnosed with depressive disorders (male= 30.2%, female=20.8%). On the other hand, only 30 consulted patients (9.7%) with a final diagnosis of depressive disorders had a previously provisional diagnosis of other psychiatric conditions (false negative). In addition, 68 consulted patients (74.7%) with a provisional diagnosis of depressive disorders were finally diagnosed with other psychiatric disorders (false positive). The sensitivity rate of the diagnosis was 43.3% (male=43.3%, female=43.5%) with a specificity rate of 80.4% (male=80.5%, female=73.2%).

- Age group and sex difference

There was no significant difference among age groups (χ^2=11.868, df=7, p=.105). The peak age of depressive disorders in men was 30-39 years old and 20-29 years old for women (see Table 4).

- Associated medical conditions

The consulted patients with a final diagnosis of depressive disorders had some medical conditions, including drug overdose or corrosive ingestion (34.0%, 18/53), trauma (22.6%, 12/53), infection (13.2%, 7/53) and cancer (11.3%, 6/53). Other medical conditions included seizures, stroke, degenerative disease and metabolic distance. Some patients had multiple medical conditions.

Psychotic disorders

- Accuracy rates, sensitivity and specificity

Among 45 consulted patients, 11 patients (24.4%) were finally diagnosed with psychotic disorders (males=27.3%, female= 21.7%). On the other hand, six patients (1.7%) with a final diagnosis of psychotic disorders had previous provisional diagnoses of other psychiatric conditions (false negative). In addition, 34 consulted patients (75.6%) with a provisional diagnosis of psychotic disorders were finally diagnosed with other psychiatric disorders (false positive). Hence, the sensitivity rate for the diagnosis of psychotic patients was 64.7% (male=54.5%, female=83.3%), while the specificity was 91.1% (male=92.9%, female=88.7%).

- Age group and sex different for psychotic disorder

There was no significant difference among age groups (χ^2=5.132, df=7, p= .644). The peak age of psychotic disorders in males was 40-49 years old, while the females were 30-39 years old as shown in Table 4. Proportions of male and female patients

referred for psychotic disorders were not significantly different (χ^2=.260, df=1, *p*=.610).

Reasons for referral and medical illnesses
Primary physicians diagnosed 64.7% (11/17) of psychotic disorder correctly. Other reasons for the referral were suicide attempts, substance use disorders, and aggressive behavior. Patients with psychotic disorders mainly had drug overdose (n=4/17, 23.5%), stroke (n=3/17, 17.6%), infection (n =3/17, 17.6%), trauma (n=2/17, 11.8%). Other medical conditions included seizures, degenerative diseases, cancer and metabolic disturbance. One patient had multiple medical illnesses.

Discussion
The consultation rate of 0.82% in our general hospital is comparable to those of other studies in Thailand (0.54% to 0.60%) [1,2], and lower than those in western countries (1.56%-3.30%) [3,4]. As in other studies [1,2,5], the consultation rates from medical and surgical departments were higher than others. Most common psychiatric disorders in this study, including adjustment disorder, delirium, substance use disorders, depression and psychotic disorders, are similar to previous studies [1,2,4].

Patients with adjustment disorder associated with suicide attempts are prevalent in patients with drug overdose or corrosive ingestion, cancer, trauma, infection (especially, HIV infection), degenerative disease, stroke, burns and seizures. In another study [6], these patients were referred significantly more often for the problems of anxiety, coping and depression. They had fewer psychiatric illnesses in the past and were rated as minimal functional impairment- all consistent with the construct of adjustment disorder, a maladaptation to a psychosocial stressor. For this diagnosis, medical staff requesting for consultation psychiatry service usually describe only the psychiatric symptoms (i.e., referred for suicide attempts or depressed mood) without the specification of the diagnosis. Although adjustment disorder was the most common final psychiatric diagnosis (35.0%) in this study, which is comparable to 24.1% to 29% in other studies [6,7]. The sensitivity rate for the diagnosis of this condition was very low (12.1%).

In this study, we found that delirium was significantly more common in older than nonconsulted patients and commonly caused by trauma, cancer, infection, stroke, degenerative disease, burns and seizures. Co-morbidity with delirium was substance use disorders, especially alcohol dependence, and most delirious patients had more than one medical problem. As in other studies, many nonpsychiatric specialists failed to recognize a majority of patients with delirium and referred for other perceived reasons such as psychotic disorders. Therefore, it may of concern that symptoms of delirium may be overlooked or misinterpreted [8]. The sensitivity rate for diagnosis of this condition was only 50.8%.

In comparison to other psychiatric disorders, the medical staff was relatively competent in recognizing substance-related disorders in the studied population. The sensitivity and specificity rate of substance use disorders were higher than other psychiatric illnesses (75% and 99.4%). The problems were more prevalent in male patients. Patients with substance-related disorders mainly had infection, trauma, seizures and stroke.

The sensitivity rate of depressive disorder was only 43.4%. In the consultation request forms, medical staff described only the psychiatric symptoms without giving any specific diagnosis. The main reason for consultation was suicide attempts. Patients with depressive disorders mainly had drug overdose or corrosive ingestion, trauma, infection, cancer, seizures, stroke, degenerative disease and metabolic disturbance. Some patients had multiple medical illnesses in which their physical symptoms

might mimic depression, e.g., fatigue, sleep difficulties and appetite disturbances.

The sensitivity rate for making a diagnosis of psychotic disorders was 64.7%. These patients mainly came up with drug overdose, stroke, infection, trauma, seizures, degenerative disease, cancer and metabolic distance. Medical staff failed to differentiate patients with psychotic disorder from delirium.

Primary physicians may be more concern on patient safety, e.g., consulted for suicidal assessment or confusion, than making a proper psychiatric diagnosis. Previous research has demonstrated that referring services focus on behavior problems rather than identifying and treating underlying psychiatric disorders [9,10].

Medically ill patients with psychiatric complications pose a great challenge to clinicians. Their behavioral disturbance and psychiatric symptoms can cause noncompliance to treatment. The findings of this study suggest that a large proportion of patients seen by medical staff have psychiatric disorders but, without psychiatric consultation, mental problems are identified in only a small number of them. Physicians should have knowledge of common psychiatric disorders such as adjustment disorder, depression, delirium, substance-related disorders and psychotic disorders. Moreover, psychiatrists should advise primary physicians on the management of these problems, in particular, suicide attempt, which can be associated with adjustment disorder, depression, substance-related disorders, psychosis and delirium. From a study report [11], ascertaining which components of suicide prevention programs are effective in reducing rates of suicide and suicide attempt is essential in order to optimize use of limited resources. All of these strategies may help promote the psychiatric care for patients with complex medical conditions, as well as foster further improvement in quality of training and research in this important area.

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ORIGINAL ARTICLE

Thailand normative data for the SF-36 health survey: Bangkok metropolitan

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Abstract
Background: The Medical Outcomes Study 36-item Short Form (SF-36) is a widely used measure of health-related quality of life. Normative data are the key to determine whether a group or an individual score above or below the average for their country, age or sex. Published norms for the SF-36 exist for other countries but have not been previously published for Thailand. *Methods:* The multi-site studies of Thai Quality of Health were the cross- sectional study involving 1,148 randomly selected Thai men and women aged 15 years or more living in Bangkok metropolitan. The information collected included the SF-36, a measure of health-related quality of life. These provided a unique opportunity to develop age- and sex-adjusted normative data for the Thai population. *Results:* Thai women scored substantially higher than men on role physical, bodily pain, role emotional and physical component summary, whereas men scored higher than women on social functioning. *Conclusion:* The scores of Bangkok people are lower than their US counterparts on all SF-36 domains, although many of the differences were not large. The differences in the SF-36 scores between age groups, sexes and countries confirm that these Thai norms are necessary for comparative purposes. The data will be useful for assessing the health status of the general population and patient populations, and the effect of interventions on health-related quality of life.

Key words: *quality of life, SF-36, normative data, Bangkok, Thailand*

Introduction

Over the past 20 years, there has been an increasing recognition of the patient's point of view as an important component of the assessment of health care outcomes. This has resulted in the development of several instruments to measure health-related quality of life. One of the most widely used and psychometrically sound instruments is the Medical Outcomes Study 36-item Short Form (SF-36) [1,2]. This relatively brief and simple questionnaire contains 36 items covering 8 health concepts chosen on the basis of reliability, validity and frequency of measurement in health surveys. Two summary scores for physical and mental health have also been developed for the SF-36 [3].

The reliability and validity of the SF-36 have been well documented by the developers of the instrument. [4-7]. A comparison of a series of generic health status measures has indicated that the SF-36 is not only psychometrically sound but is also more responsive to clinical improvement

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than the other instruments [8,9]. Moreover, health functioning changes in the hypothesized direction with increasing age, socioeconomic status and disease status in a population-based longitudinal study of the SF-36, which suggests that the instrument is sensitive to changes in assessing the health of the general population [10].

A Thai version of the SF-36 has been successfully constructed with apparent equivalence to the original SF-36 and with an acceptable level of reliability [11]. Establishing norms is an important step in the translation and cultural adaptation of a scale. Because the absolute number of a scale score has little meaning by itself, norms provide anchors to interpret an individual's or a group's score in relation to those of others [12].

Furthermore, normative data are the key to determine whether a group or an individual scores below or above the average for their country, age or sex. Published norms now exist for the United States [13], the Queensland region of Australia [14], the United Kingdom [15,16]. Comparable norms do not yet exist in the Thai population. This forces researchers and policy-makers to compare data from Thai studies to those from other countries. This study aimed to present the normative data of Thai SF-36 obtained from a randomly selected sample of women and men aged 15 years or more living in Bangkok Metropolitan.

Methods

The sample was pooled from the normal control subjects included in previous studies using SF-36 [17-20]. All of these studies were carried out in Bangkok Metropolitan. Individuals aged 15 years or more were included. Sociodemographic characteristics of the sample were collected by means of an interviewer-administered questionnaire. Health status was measured by self-administered Thai SF-36 at the end of the interview.

The SF-36 contains 36 items that, when scored, yield eight domains. Physical functioning (10 items) assesses limitations of physical activities such as walking and climbing stairs. The role physical (4 items) and role emotional (3 items) domains measure problems related to work or other daily activities, which are the results of physical health and emotional problems, respectively. Bodily pain (2 items) assesses limitations due to pain, and vitality (4 items) measures energy and tiredness. The social functioning domain (2 items) examines the effect of physical and emotional health on normal social activities. Mental health (5 items) assesses happiness, nervousness and depression. The general health perceptions domain (5 items) evaluates personal health and the expectation of changes in health. All domains are scored on a scale of 0 to 100, with 100 representing the best possible health state. One additional, the unscored item compares the respondent's assessment of her or his current health with that of one year before. Summary scores for a physical component (physical functioning, role physical, bodily pain and general health perceptions) and a mental component (vitality, social functioning, mental health and role emotional) can also be derived.

Table 1: Characteristics of the sample

Sample characteristic	N (1148)	%
Sex		
Male	436	38.0
Female	712	62.0
Age (15-77 years)		
Mean age 36.3 (SD12.5)		
15-24	239	20.8
25-34	311	27.1
35-44	268	23.3
45-54	217	18.9
>=55	113	9.8
Education		
Primary school	39	3.6
Secondary school	401	37.1
High school	254	23.5
College	120	11.1
Undergraduate	214	19.8
Graduate	54	5.0

Sample characteristics are presented descriptively (frequencies and percentages). In order to perform a gender comparison, independent t-tests were carried out. To determine the differences between age groups, one-way ANOVA was conducted.

Results

Characteristic of the sample (see Table 1)

Data were collected between January 2001 and June 2003. All of the 1,148 subjects were the control cases that had completed the Thai SF 36. Their mean age was 36.3 (SD 12.5), range 15-77 years. Approximately, 38% of the samples were men with a mean age of 36.1 [SD 12.8] years, range 15-77 years, and 62% were women with a mean age of 36.4 [SD 12.4] years, range 15-73 years.

The standardized scores for the eight domains and the two summary scales (physical component and mental component) of the SF-36 varied with age (see Table 2). The group of 55-77 years had lower scores than other age groups in four domains

Table 2: Mean ± SD, (95% CI) scores of the 8 domains of SF-36 of Bangkok people

SF 36	Age group					p-value
	15-24	**25-34**	**35-44**	**45-54**	**≥ 55**	
	n=239	*n=311*	*n=268*	*n=217*	*n=113*	
Physical Functioning	73.5±20.8 (70.9-76.2)	76.8±18.9 (74.7-78.9)	72.1±20 (69.7-74.5)	72.5±20.8 (69.7-75.3)	59.7±25.4 (55.0-64.5)	.000
Role physical	81.8±25.8 (78.5-85.1)	88.1±21.0 (85.8-90.4)	83.0±25.4 (80.0-86.1)	81.4±27.6 (77.8-85.1)	65.9±38.5 (58.7-73.1)	.000
Bodily pain	71.1±15.5 (69.1-73.0)	73.3±16.6 (71.5-75.2)	71.7±16.6 (69.7-73.7)	71.6±20.7 (68.8-74.4)	60.0±26.6 (55.0-65.0)	.000
General health perceptions	63.3±16.2 (61.3-65.4)	65.5±16.7 (63.7-67.4)	62.7±16.5 (60.7-64.7)	63.2±17.7 (60.9-65.6)	60.4±17.1 (57.2-63.6)	.716
Vitality	62.9±13.6 (61.2-64.6)	65.2±13.3 (63.7-66.7)	62.2±13.4 (60.6-63.9)	64.4±15.2 (62.4-66.4)	61.3±14.0 (58.7-63.9)	.130
Social functioning	67.3±17.3 (65.0-69.5)	68.3±18.0 (66.3-70.3)	69.1±18.8 (66.8-71.3)	64.3±22.6 (61.3-67.4)	68.4±25.5 (63.6-73.1)	.355
Role emotional	73.4±32.1 (69.3-77.4)	79.2±30.8 (75.8-82.6)	76.0±34.0 (71.9-80.1)	81.7±28.5 (77.9-85.5)	66.7±40.3 (59.1-74.2)	.001
Mental health	70.4±13.7 (68.6-72.1)	73.0±13.4 (71.5-74.5)	69.7±14.2 (68.0-71.4)	70.6±16.4 (68.5-72.8)	69.0±15.3 (66.1-71.8)	.442

Table 3: Mean ± SD scores of the Thailand normative data for the 8 domains of SF-36

SF 36	Male	Female	p-value
	n=436	*n=712*	
Physical functioning	72.98 (20.84)	72.25 (21.25)	.56
Role physical	79.59 (28.40)	83.74 (26.11)	.013
Bodily pain	68.29 (18.84)	72.42 (18.59)	.001
General health perceptions	63.11 (16.12)	63.72 (17.30)	.54
Vitality	64.06 (13.94)	63.17 (13.83)	.29
Social functioning	70.53 (19.61)	65.68 (19.76)	.001
Role emotional	73.47 (33.63)	78.32 (32.02)	.015
Mental health	70.47 (14.72)	71.06 (14.35)	.5

Table 4: Mean ± SD (95% CI) scores of the Thailand normative men data for the 8 domains of SF-36 health survey: Bangkok metropolitan

SF 36	Age group					p-value
	15-24 *n=101*	**25-34** *n=107*	**35-44** *n=99*	**45-54** *n=83*	**55-64** *n=46*	
Physical functioning	71.5±21.4 (67.3-75.8)	76.9±18.8 (73.3-80.5)	73.3±20.1 (69.3-77.3)	75.1±20.0 (70.7-79.4)	62.7±24.2 (55.5-69.9)	.003
Role physical	77.5±28.4 (71.9-83.1)	87.4±20.1 (83.5-91.2)	81.3±26.6 (76-86.6)	77.4±30.9 (70.7-84.2)	66.3±37.7 (55.1-77.5)	.001
Bodily pain	70.4±14.9 (67.4-73.3)	70.5±16.2 (67.4-73.6)	71.1±14.5 (68.2-74.0)	66.9±21.6 (62.2-71.6)	54.9±28.1 (46.5-63.2)	.000
General health perceptions	65.0±15.8 (61.9-68.2)	64.7±14.4 (61.9-67.4)	63.4±17.2 (59.9-66.8)	59.9±17.0 (56.2-63.6)	60.4±15.8 (55.7-65.1)	.130
Vitality	64.8±13.8 (62.1-67.5)	65.1±13.2 (62.6-67.7)	63.6±14.7 (60.6-66.5)	64.1±14.6 (60.9-67.3)	60.9±13.2 (57-64.8)	.487
Social functioning	67.9±16.7 (64.6-71.2)	74.1±18.3 (70.6-77.6)	73.6±17.2 (70.2-77.0)	68.4±22.4 (63.5-73.3)	65.2±25.4 (57.7-72.8)	.016
Role emotional	70.3±33.0 (63.8-76.8)	78.2±29.7 (72.5-83.9)	72.7±35.4 (65.7-79.8)	77.5±30.8 (70.8-84.2)	63.8±42.1 (51.3-76.3)	.088
Mental health	70.1±14.4 (67.3-72.9)	72.4±14.3 (69.6-75.1)	70.1±14.9 (67.1-73.0)	69.1±16.4 (65.5-72.7)	70.2±12.8 (66.4-74.0)	.618

Table 5: Mean ± SD (95% CI) scores of the Thailand normative women data for the 8 domains of SF-36 health survey: Bangkok metropolitan

SF 36	Age group					p-value
	15-24 n=138	**25-34** n=204	**35-44** n=169	**45-54** n=134	**55-64** n=67	
Physical Functioning	75.0±20.2 (71.6-78.4)	76.7±19.0 (74.1-79.4)	71.4±20.0 (68.4-74.4)	71.0±21.3 (67.3-74.6)	57.7±26.1 (51.3-64.1)	.000
Role physical	85.0±23.3 (81-88.9)	88.5±21.5 (85.5-91.5)	84.0±24.8 (80.3-87.8)	84.0±25.2 (79.7-88.3)	65.7±39.4 (56.1-75.3)	.000
Bodily pain	71.6±15.9 (68.9-74.3)	74.8±16.7 (72.5-77.1)	72.1±17.8 (69.4-74.8)	74.5±19.7 (71.1-77.9)	63.5±25.2 (57.4-69.7)	.000
General health Perceptions	62.1±16.5 (59.3-64.9)	66.0±17.9 (63.5-68.5)	62.3±16.1 (59.9-64.8)	65.3±17.9 (62.3-68.4)	60.4±18.1 (56-64.8)	.049
Vitality	61.5±13.4 (59.3-63.8)	65.2±13.4 (63.4-67.1)	61.5±12.5 (59.6-63.4)	64.6±15.6 (62-67.3)	61.6±14.5 (58.1-65.2)	.022
Social functioning	66.8±17.7 (63.8-69.7)	65.3±17.1 (62.9-67.6)	66.4±19.2 (63.5-69.3)	61.8±22.4 (58-65.7)	70.5±25.5 (64.3-76.8)	.043
Role emotional	75.6±31.3 (70.3-80.9)	79.7±31.4 (75.4-84.1)	77.9±33.1 (72.9-82.9)	84.3±26.7 (79.8-88.9)	68.7±39.3 (59.1-78.2)	.015
Mental health	70.6±13.3 (68.3-72.8)	73.3±12.9 (71.5-75.1)	69.4±13.9 (67.3-71.5)	71.6±16.3 (68.8-74.4)	68.1±16.9 (64-72.2)	.035

including physical functioning, role physical, bodily pain and role mental. Women had higher scores than men in role physical, bodily pain, social function and role emotional. (Table 3). When men and women data were separately analyzed we found that the influence of age on each domain score was different between genders. There were significant differences among age grounds on the scores of all

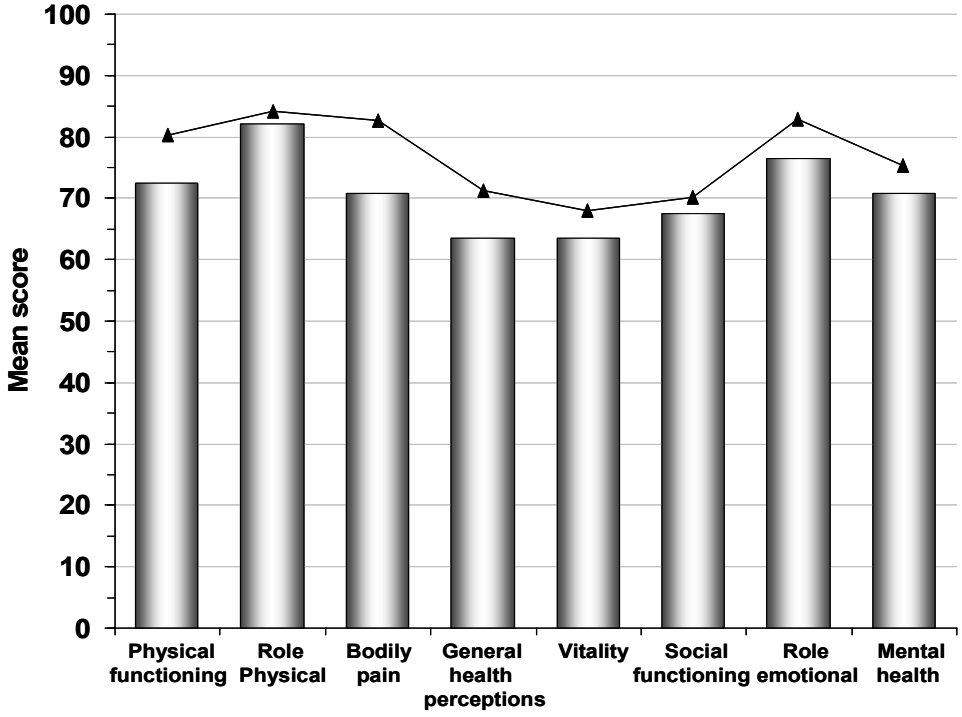

Figure 1: Mean scores for the Thai versus US normative data for the 8 domains

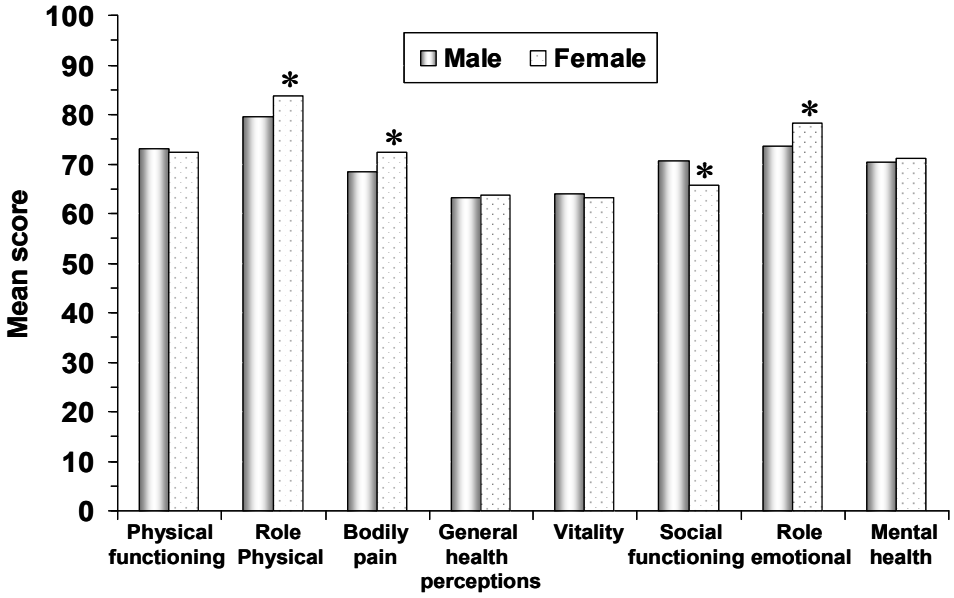

Figure 2: Mean age- and sex-standardized SF-36 and summary scale scores for Thai men (dark grey bars) and women (light grey bars). * is a statistically significant difference between men and women ($p<.05$)

domains in women (Table 4), but only four domains in men showed the significant differences of scores among age groups. (Table 5).

Figure 1 shows the comparison of the SF-36 normative data of Thai population living in Bangkok Metropolitan and the normative data of United State. The Thai norms were lower than the US norms in all eight domains, although many of the differences were not large.

The age- and sex-standardized scores for Thai men and women varied with age and sex (Tables 3 and 4). As in the entire sample, several domains exhibited a ceiling effect (87.4% for men and 88.5% for women in the role physical domain), but a strong floor effect did not clearly shown (51.3 % for women in physical functioning and 51.3 for men in the role emotional domain).

The mean scores of Thai men and women are shown in Figure 2. Men scored nonsignificantly higher than women on physical functioning and social functioning of the SF-36. Thai women scored substantially and statistically significantly higher than men on role physical, bodily pain, role emotional and social functioning ($p < .05$).

Discussion

Normative data for the SF-36 have been obtained from the normal control subjects included in previous studies. All of these studies were carried out in Bangkok Metropolitan and could be used as an important basis in comparison to future studies.

By the use of SF-36, Thais have relatively lower scores than the US counterpart on all eight domains and two summary scales. The differences between these two groups may be due to the methodological differences rather than representing the true differences. For example, the US normative data are based not on a random sample but, rather, on the responses of 2,474 participants in the National Survey of Functional Status, who were selected to receive a mailed version on the basis of previous participation in a General Social Survey. These differences in methodology will introduce variation in the normative data for international comparisons. Thus, a clear description of methods is a vital part of the interpretation of normative data.

The variability of the scores by age underscores the need of appropriate age-specific normative data.

There are differences between men and women in the Thai sample. Women scored substantially and significantly higher than men on role physical, bodily pain, role emotional and social functioning. This differs from those found in Norway [21], Turkey [22] and Canada [23], in which men had nonsignificantly higher scores than women on all domains.

This study is the first normative data of SF-36 in Thailand. However, our results could not be generalisable to the whole Thai population because our study sample was a pooled sample from previous SF-36 studies in Bangkok.

In conclusions, the differences of the SF-36 scores between age groups, sexes and countries confirm that these Thai norms are necessary for comparative purposes. These data are useful on the assessment of health status of the general population and of the patient populations, as well as the effect of interventions on the health-related quality of life.

Conflict of interest: none

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