Journal of Human Hypertension (2006) 20, 23–29

www.nature.com/jhh

ORIGINAL ARTICLE

Identification of psychosocial factors of noncompliance in hypertensive patients

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This cross-sectional study was aimed to identify the predictors of medication noncompliance in hypertensive patients. The study was conducted at the Family Medicine Clinic, Hospital Universiti Sains Malaysia, Kelantan, Malaysia, which is a university-based teaching hospital. All hypertensive patients aged 40 or over registered from January to June 2004, who had been on treatment for at least 3 months, were screened. Previously validated self-administered questionnaires were used to assess the compliance and psychosocial factors. A total of 240 hypertensive patients were recruited in the study. Of these, 55.8% were noncompliant to medication. Logistic regression showed that age (adjusted odds ratio (OR): 0.96; 95% confidence interval (CI): 0.92–0.997; *P*: 0.035), patient satisfaction (adjusted OR: 0.97; 95% CI: 0.93–0.998; *P*: 0.036) and medication barrier (adjusted OR: 0.95; 95% CI: 0.91–0.987; *P*: 0.009) were significant predictors of medication noncompliance. Therefore, younger age, poor patient satisfaction and medication barrier were identified as independent psychosocial predictors of medication noncompliant in hypertensive patients.
Journal of Human Hypertension (2006) **20,** 23–29. doi:10.1038/sj.jhh.1001930; published online 22 September 2005

Keywords: medication noncompliance; psychosocial factors; patient satisfaction

Introduction

Blood pressure (BP) is a major risk factor for developing coronary heart disease, stroke and congestive heart failure. He and MacGregor,[1] in a meta-analysis study, demonstrated that 125 600 events (nonfatal stroke or ischaemic heart disease) could be prevented each year in the UK if all UK hypertensives reduced their systolic BP to <140 mmHg. The primary goal in treating hypertension is to achieve optimal BP levels, thereby reducing the risks of cardiovascular morbidity and mortality.[2,3] However, despite the expanding choices in antihypertensive treatments, less than one-third of hypertensive adults have their BP adequately controlled in the United States.[4]

In Malaysia, the Second National Health Morbidity Survey reported that the prevalence of hypertension among adults aged 30 years and above was 29.9%, of whom 32.6% had stopped treatment since diagnosis. The main reasons given for noncompliance are predominantly based around poor communication. These include the perception that hypertension was not a serious illness, the patient had been cured or that treatment was no longer required.[5] Another Malaysian study has shown that the commonest cause of resistant hypertension requiring admission is noncompliance.[6]

Compliance describes the extent to which a person's behaviour coincided with medical advice.[7,8] Compliance has been evaluated from a wide range of scientific and clinical perspectives since the 1950s. Compliant patients are defined as those who accept their physician's advice to start drug therapy and who take their medication at least 80% of the time.[9,10] Noncompliance means constant

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Received 20 June 2005; revised 11 July 2005; accepted 12 July 2005; published online 22 September 2005

neglect rather than just temporary forgetfulness or neglect of treatment.[3]

Medication noncompliance is a serious healthcare concern and has provided challenges to the healthcare providers.[11] However, despite considerable effort to improve patient compliance, noncompliance continues to be a significant problem.[12,13] When medications are used incorrectly or not taken at all, healthcare providers' time, effort and expertise are wasted. Furthermore, noncompliance may impair patients' quality of life, make the condition more difficult to treat, may cause further complications such as cardiovascular and renal diseases and a financial strain to health management.[14–16]

Psychosocial factors related to noncompliance are well-recognized problems, and have been documented in literature with mixed results. Studies have suggested that age,[17,18] sex,[18] lower socioeconomic status, severity of disease,[17] drug choice,[7,19,20] number of medications prescribed,[18,19] drug tolerability,[7,20] regimen complexity,[18,20] co-morbid medical conditions,[17,19] family support,[21] self-efficacy, intention to comply,[22] physician–patient relationship,[23] satisfaction with health care[24] and depression[25,26] are associated with compliance. However, some of these studies are limited by specific race,[17,24] usage of nonvalidated tools,[22] and failure to exclude newly diagnosed patients and patients with co-existing medical illnesses.[23]

Factors contributing to noncompliance may vary from country to country and may contribute to the variations of the results in the published studies. Furthermore, compliance is a dynamic phenomenon and its degree may vary over time. Hence, identification of factors contributing to noncompliance is very critical for effective planning and performing intervention strategies. Hypertension is the disease in which compliance and persistence have been best studied,[18] and it served as a model in our study. It is the objective of the study to identify psychosocial predictors of medication noncompliance in hypertensive patients using valid and reliable questionnaires.

Materials and methods

All patients registered at the Family Medicine Clinic, Hospital Universiti Sains Malaysia, Kelantan, Malaysia, from January to June 2004 were screened based on medical records. Patients were eligible for the study if they fulfilled these inclusion criteria: essential hypertension, on antihypertensive medication for at least 3 months, aged 40 years old and above, on at least one antihypertensive medication and not more than three antihypertensive medications, and agreed to participate in the study. Patients were excluded if they were pregnant, had secondary hypertension, renal impairment, impaired liver function, other concomitant diseases such as diabetes mellitus, ischaemic heart disease, congestive cardiac failure, cerebro-vascular accident, bronchial asthma, chronic obstructive pulmonary disease and BP of 200/120 mmHg or more.

Eligible patients were asked basic information of their illness to confirm their fitness for the study. Patients who agreed to participate were given information about the study and asked to sign consent forms. Patients were then given validated compliance questionnaire and psychosocial questionnaire to complete while they were waiting to see their doctors. Questionnaires typically took 15–40 min to complete. Patients who had difficulty in reading were assisted in completing the questionnaire. This study was approved by the Universiti Sains Malaysia Research and Ethical Committee on March 2003.

Compliance assessment

The compliance questionnaire was developed and validated in two separate pilot studies of 60 patients each. The questionnaire consisted of two domains: a drug-taking behaviour domain comprising seven items and drug-stopping behaviour domain comprising three items. Internal consistency reliabilities (Cronbach's alpha) were 0.67 and 0.84, and test–retest single measure intraclass correlation coefficients were 0.78 and 0.93, respectively, for each domain. Possible scores on the scale ranged from 1 to 5, with 1 indicating 'never' and 5 indicating 'very frequent'. All negatively worded scores were reversed and all scores were converted to a 0 to 100 scale. Patients were categorized as 'compliant' if they had an individual score of 75% or greater,[27] which corresponded to being compliant 'frequently' and 'very frequently' for all the items in the questionnaire.

Psychosocial assessment

The psychosocial questionnaire consisted of 35 items in eight psychosocial domains: lifestyle, emotional state, attitude, understanding, motivation, perception of susceptibility, perception of severity, and barriers to compliance. The questionnaire was developed and validated in two separate pilot studies of 60 patients each. The Health Belief model and its modified version,[27,28] which were widely used to study patients' responses to symptoms and their behaviour in response to diagnosed illness, particularly compliance with medical regimens, were mainly used in the development of the questionnaire. Cronbach's alpha ranged from 0.42 (patient barrier) to 0.87 (emotional state), and the test–retest single measure intraclass correlation coefficient was 0.53 (communication barrier) to 0.77 (perception of severity). The questionnaire was scored using a 5-point Likert scale from 1 (never, extremely do not believe, very untrue) to 5 (very frequent, extremely believe, very true). Scores were obtained by reversing the negatively worded items on each domain, computing total scores for

each domain, and computing and transforming the raw total scores to a 0 to 100 scales.

A lifestyle score was calculated based on assessment of the participants' exercise, diet and smoking habits. Alcohol intake was not included in the assessment since the majority of patients (97.5%) in the study did not take alcohol. Emotional state score was measured as reported frequency of depression, anxiety and stress within the past 3 months. Attitude items measured patients' confidence with the doctor's capability, how patients liked the doctor and whether patients liked taking their medication. Understanding referred to the patients' perception of the cause of hypertension, and information given by doctors and pharmacists. Motivation assessed whether patients were tired of continuing their medication, liked coming to clinic/hospital, were influenced by families/friends not to take their medications and whether patients were angry with the treating doctors. Perception of susceptibility assessed patients' perception of the possible causes of hypertension. Perception of severity addressed patients' perception that their medication would interact adversely with traditional medicines they were taking or with food. Barriers to compliance were divided into four subdomains: medication barrier, patient barrier, communication barrier, and logistic and transportation barrier. Higher scores in these domains revealed healthier lifestyle, better emotional state, more positive attitude, better understanding, greater motivation, higher perception of susceptibility, higher perception of severity or lesser barriers.

Patient satisfaction was evaluated separately using Patient Satisfaction with Health Care (PSHC) Questionnaire, which was developed and validated in two separate pilot studies. The PSHC questionnaire comprised of four domains, which consist of overall patient satisfaction, satisfaction with appointment, satisfaction with doctor service and satisfaction with pharmacy service. Items were scored using a 5-point Likert scale from 1 (very dissatisfied) to 5 (very satisfied). The internal consistency reliabilities ranged from 0.76 (satisfaction with appointment) to 0.91 (satisfaction with pharmacy), and test–retest single measure intraclass correlation coefficients ranged from 0.54 (satisfaction with appointment) to 0.70 (satisfaction with pharmacy). Scores were obtained by reversing the negatively worded items on each domain, computing total scores for each domain, and computing and transforming the raw total scores to a 0 to 100 scale. Higher scores indicated greater satisfaction.

Statistical analysis

Demographic data are presented as percentages and means with standard deviations (s.d.). Associations between noncompliance and other factors were first examined using univariate logistic regression method. Then, multiple logistic regression analysis was conducted to determine the independent associations between noncompliance and independent variables. The selection of variables to include in the multiple logistic regression model was based on results from the simple regression method, clinical importance and results found in literature, and stepwise variable selection methods were applied. The most relevant results were adjusted odds ratios (ORs) of medication noncompliance for different independent variables with 95% confidence intervals (CIs). All *P*-values were two-tailed, and $P<0.05$ was considered statistically significant. Analyses were performed using SPSS statistical software version 11 (SPSS Inc., Richmond, CA, USA).

Results

A total of 246 hypertensive patients were eligible for the study, and 242 (98%) patients agreed to participate. Among them, 240 (99%) completed the questionnaires. The majority of the participants

Table 1 Demographic characteristic of study sample

Variable	n	*Frequency (%)*	*Mean*	*s.d.*
Gender				
Male	120	50.2		
Female	119	49.8		
Age (years)	236		54.5	8.49
Height (m)	230		1.6	0.68
Weight (kg)	230		66.9	11.40
BMI	229		26.5	4.17
Race				
Malay	210	87.9		
Chinese	28	11.7		
Others	1	0.4		
Marital status				
Married	220	92.8		
Single	2	0.8		
Divorced	15	6.3		
Household income				
Low <RM 450.00	39	16.9		
Medium RM 450.00–1500.00	106	45.9		
High >RM 1500.00	86	37.2		
Formal education				
Primary education and lower	61	25.9		
Secondary education	43	60.6		
Tertiary education	32	13.6		
Smoking				
Yes	35	14.7		
No	204	85.4		
Alcohol ingestion				
Yes	6	2.5		
No	233	97.5		
Duration of hypertension in months	223		98.2	76

Table 2 Predictors associated with noncompliance (simple and multiple logistic regression analysis)

	Simple logistic regression		*Multiple logistic regression*	
Independent variable	*Crude OR (95% CI)*	P-*value*[a]	*Adjusted OR (95% CI)*	P-*value*[a]
Age (years)	0.96 (0.93, 0.99)	0.012	0.96 (0.92, 0.997)	0.035
Gender				
Male	1.00			
Female	1.26 (0.76, 2.10)	0.371		
Race				
Malay	1.00			
Others	1.23 (0.57, 2.83)	0.566		
BMI	0.96 (0.90, 1.02)	0.227		
Marital status				
Married	1.00			
Unmarried	0.70 (0.26, 1.87)	0.471		
Household income				
Low <RM 450.00	1.00			
Medium RM 450.00–1500.00	1.12 (0.53, 2.40)	0.764		
High >RM 1500.00	1.30 (0.60, 2.85)	0.507		
Education				
Primary education and lower	1.00			
Secondary education	1.30 (0.71, 2.36)	0.398		
Tertiary education	2.07 (0.86, 4.99)	0.106		
Duration of hypertension in months	1.00 (0.99, 1.00)	0.132		
Systolic BP				
140 mmHg and lower	1.00 (0.99, 1.01)	0.968		
141 mmHg and higher	1.00			
Diastolic BP				
90 mmHg and below	1.01 (0.98, 1.04)	0.545		
91 mmHg and higher	1.00			
Lifestyle score	0.99 (0.97, 1.02)	0.516		
Emotional state score	0.99 (0.97, 1.00)	0.152		
Attitude score	0.99 (0.97, 1.02)	0.604		
Understanding score	1.00 (0.98, 1.03)	0.972		
Motivation score	1.00 (0.98, 1.02)	0.960		
Perception of susceptibility score	1.01 (0.99, 1.03)	0.287		
Perception of severity score	0.99 (0.98, 1.01)	0.216		
Patient satisfaction				
(I) Overall satisfaction score	0.97 (0.95, 1.00)	0.056	0.97 (0.93, 0.998)	0.036
(II) Satisfaction with appointment score	0.98 (0.96, 1.00)	0.096		
(III) Satisfaction with doctor score	0.99 (0.96, 1.01)	0.321		
(IV) Satisfaction with pharmacy score	1.00 (0.97, 1.02)	0.765		
Barriers to compliance				
(I) Medication barrier				
(a) Taste and smell score	0.99 (0.97, 1.00)	0.100		
(b) Colour, brand name, size, and adverse drug reaction score	0.98 (0.96, 1.01)	0.131		
(c) Complex regime, cost, and effectiveness score	0.96 (0.93, 0.99)	0.014	0.95 (0.91, 0.99)	0.009
(II) Patient barrier score	0.99 (0.98, 1.01)	0.371		
(III) Communication barrier score	0.99 (0.98, 1.01)	0.416		
(IV) Logistic and transportation barrier score	1.01 (1.00, 1.03)	0.122		

Dependent variables: compliance (0 = compliance, 1 = noncompliance).
[a]LR test.

(88%) were Malay, married, with the mean age of 55 years (s.d. 8.5), and there were equal number of men and women. The medication noncompliance rate was 55.8%. The characteristics of the participants are shown in Table 1.

Multiple regression analysis (Table 2) indicated that noncompliance was associated with age (adjusted OR: 0.96; 95% CI: 0.92–0.997; *P*: 0.035), overall patient satisfaction (adjusted OR: 0.97; 95% CI: 0.93–0.998; *P*: 0.036) and medication barrier: complex regime, cost, effectiveness (adjusted OR: 0.95; 95% CI: 0.91–0.987; *P*: 0.009). There was no association between noncompliance and other sociodemographic variables, lifestyle, emotional state, attitude, understanding, motivation, perception of susceptibility and perception of severity. For the model tested, there was no evidence on interaction among the independent variables.

Discussion

Poor medication compliance was frequent in our hypertensive patients and the overall noncompliance rate measured in our study was consistent with other studies.[10,29–33] Iskedjian *et al*.[30] in a meta-analysis study reported that rates of compliance to pharmacotherapy ranged from $<5\%$ to $>90\%$. Aziz and Ibrahim,[31] in a previous Malaysian study, reported 56% noncompliance in patients with chronic diseases such as hypertension, ischaemic heart disease, diabetes and bronchial asthma. In another study, Supramaniam[32] found that more than 59% of hypertensive patients did not adhere to the medications prescribed.

Predictors of noncompliance identified from our study were age, overall patient satisfaction and medication barrier (complex regime, cost, effectiveness). These results were inconsistent with the findings from another local study which found that none of these variables were significantly related to compliance, except adequacy of BP control.[34] However, a structured interview was utilized with no information given on inter-rater and intra-rater reliability of the questionnaire.

In agreement with Bloom,[18] age was found to be significantly and independently associated with noncompliance. Compliance with antihypertensive drugs was better in older hypertensive patients.

Our study confirmed previous findings (Tables 3, 4), demonstrating that poor PSHC was significantly and independently associated with poor medication compliance.[24,35] Renzi *et al*.[35] reported that treatment adherence was strongly associated with complete satisfaction in dermatologic patients. However, Wang *et al*.[25] found no association between PSHC and compliance.

Medication barrier, which was represented by complex regime, cost, and effectiveness, were found to be inversely associated with compliance and this result was consistent with other findings.[18–20] Monane *et al*.,[19] in a retrospective study of 8643 hypertensives, found that good compliance was inversely correlated with the use of multiple drugs and the number of medications prescribed.

Wang *et al*.[25] found significant association between depression and noncompliance in hypertensives. Although this study demonstrated depression as a multivariate predictor of noncompliance, this was not confirmed in our study. The lack of correlation between emotional state and noncompliance in our study may be related to the homogenous nature of our study population. Newly diagnosed patients and patients with other concomitant diseases including depression were excluded from our study. This inconsistency might also be due to different setting, time and measurement tools used in the study.

The findings of this study have several limitations. Self-reporting was used as the only measure of compliance, and this may lead to overestimation.[36] Lim *et al*.[34] reported only 71% sensitivity and 50% specificity of self-report as a measure of compliance when compared with pill count. A combination of self-report and objective measures may yield a higher accuracy concerning compliance behaviours. The use of objective measures like pill counts, serum bioassays and BP controls in conjunction with self-report should be explored in future compliance studies.

Furthermore, the cross-sectional design used in the study might not capture the compliance rates accurately. The best method for evaluating compliance in hypertensive patients is long-term observation.[3]

Table 3 Current concepts in compliance

- Compliance is a dynamic phenomenon and its degree may vary over time, place and population.
- Psychosocial factors related to noncompliance are well-recognized problems and have been documented in literature, but with mixed results.
- Studies have suggested that age, sex, lower socioeconomic status, severity of disease, drug choice, number of medication prescribed, drug tolerability, regimen complexity, co-morbid medical conditions, family support, self efficacy, intention to comply, physician–patient relationship, satisfaction with health care and depression are associated with compliance.
- However, some of these studies are limited by specific race, usage of nonvalidated tools and failure to exclude newly diagnosed patients and patients with co-existing medical illnesses.

Table 4 What this study adds

- Identified psychosocial predictors of medication noncompliance in hypertensive patients using valid and reliable questionnaires.
- Study population is a highly homogenous sample and controlled for the presence of concomitant diseases, number of medication and severity of hypertension.
- Patient satisfaction, age and medication barrier have been identified as predictors for medication noncompliance in our population.

Cohort studies with more frequent follow-ups and larger sample size might yield a more reliable result since other researchers found that medication noncompliance worsened over time.[37,38]

In conclusion, younger age, poor patient satisfaction and medication barrier (complex regime, cost, effectiveness) were identified as psychosocial predictors of medication noncompliance in hypertensive patients. Identification of multiple factors that predict noncompliance will allow healthcare providers to plan and implement various intervention strategies to improve medication compliance.

Acknowledgements

This study is supported by a grant from the Intensification of Research in Priority Area (IRPA), Ministry of Science, Technology and Innovation, Malaysia (IRPA 305/PPSP/6140023).

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