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Is cognitive impairment a risk factor for poor compliance among Japanese elderly in the community?

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Abstract Objective: The association between cognitive impairment and compliance with prescribed medications was investigated among functionally independent Japanese elderly in the community.

Subjects: The subjects of this study were 220 elderly persons aged 60 years and over, who lived in the community. All participants were taking a regimen of one or more prescribed drugs. We included elderly with mild to moderate cognitive impairment. Medication use was observed by pharmacist-conducted interviews during home visits. Compliance was estimated by the pill count method. The Mini-Mental State Examination (MMSE) was used to estimate cognitive function.

Results: The mean age (SD) of the subjects was 75.7 (6.9) years. Of the subjects, 58 (26.4%) were cognitively impaired (MMSE \leq 23), and 76 (34.6%) exhibited poor compliance (rate of compliance $<$ 80%). Poor compliance was associated with the subjects who had a lower education level, had lower MMSE scores, had concern about taking drugs, who intentionally self-selected (intentional noncompliance) prescribed drugs, had a poor relationship with a physician, who did not have one dose package, and those who did not use a medical calendar. In multiple logistic regression analyses, intentional noncompliance (OR 19.65, 95%, CI 9.22–41.92; OR, odds ratio; CI, confidence interval), cognitive impairment (MMSE \leq 23; OR 2.94, 95%, CI 1.32–6.58), and a poor relationship with a physician (OR 6.24, 95%, CI 1.55–25.20) were independent predictors of poor compliance for elderly in the community.

Conclusion: We found that cognitive impairment was one of the predictors for poor compliance among the

elderly who are functionally independent in the community. Intentional noncompliance was the strongest predictor for poor compliance, which was influenced by the relationship between patient and physician. Physicians should establish good communication with their elderly patients and provide some support to compensate for cognitive impairment.

Keywords Cognitive impairment · Medication compliance · Elderly in the community · Intentional noncompliance

Introduction

People over the age of 65 years accounted for 17.2% of the Japanese population in 2000 [1]. Moreover, there were 1.56 million cognitively impaired elderly in Japan in 2000 (7.2% of the people over the age of 65 years), and it is estimated that there will be 2.62 million (8.4%) in 2015 [2]. Thus, many elderly residing in the community may not have the cognitive ability to manage their medication regimens properly [3].

An older patient is more likely to have multiple diseases, which may require several medications [3, 4, 5]. However, multiple medication use was reported to increase the risk of adverse drug events and noncompliance [6, 7]. Some studies have shown that the rate of medication compliance with long-term therapy was only 40–60% in elderly people [4, 8, 9]. Medication noncompliance among elderly persons may result in declining health, increased costs for health care, and increased preventable hospital admission [10] or emergency department visits [11, 12]. Approximately 70% of medication-related emergency department visits were reported to be preventable, and 46% of preventable medication-related visits were due to noncompliance [12].

Previous studies of elderly persons living in the community reported that noncompliance with medication regimens correlates with age [13, 14], total number of prescribed drugs [15, 16], forgetfulness [17, 18], lack of

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knowledge about the drugs [19], intentional noncompliance due to an adverse reaction and undesired outcome [14], belief about the dangers of dependence or long-term effects of medications [20], and a poor relationship with a physician or a pharmacist [4, 21, 22].

In our previous study [21], dealing with elderly home-care recipients, we reported that poor compliance was associated with no pharmacist counseling, frequency of meals, and age. In that study we excluded patients who were severely cognitively impaired as judged according to a mental status questionnaire (MSQ) [23]. However, there are many elderly who are independent and lead an active daily life despite impaired cognition. So we focused on these elderly in the community. Cognitive impairment may also put such persons at risk for medication noncompliance [24, 25, 26] or limit their ability to self-administer medication [27]. Few studies, however, have examined the association between cognitive function and medication compliance among elderly persons living in the community, and some studies [17, 28] failed to find any relation between cognitive function and compliance.

The purpose of this study was to examine whether cognitive impairment is a risk factor for noncompliance with prescribed drug regimens among functionally independent elderly living in the community.

Subjects and methods

The study was a cross-sectional survey of people over 60 years of age, who were living in the community, were functionally independent, were taking a regimen of one or more prescribed drugs, agreed to participate in this study, and gave informed consent. The study was conducted from November 1998 through October 2000 in three communities near the University of Tsukuba, all in the Ibaraki Prefecture, 50 km north of Tokyo in Japan. The population of elderly people aged 65 and over in the three cities was between 11.8% and 17.6%.

We recruited participants for this study in health education classes held for the regional senior groups by a physician or public health nurses. There are 20 to 30 regional senior groups in each town. Each group consists of approximately 30 to 50 members, of which about one third attends the health education classes. Elderly subjects who were bedridden or had severely impaired cognition according to a mental status questionnaire [23] were excluded from the analysis (see results). We included participants with mild to moderate cognitive impairment, different from our previous study. The interviews were carried out by a pharmacist–investigator at the homes of the subjects. There the investigator conducted a face-to-face interview based on a questionnaire and counted tablets to test for medication compliance. The questionnaire included the following items: age, gender, Barthel index [an assessment scale for activities of daily living consisting of 10 fields with scores from 0 (worst) to 100 (best) points] [29], history of cerebral infarction, eyesight (3-point scale; 3: poor, 1: good), hearing ability (3-point scale; 3: poor, 1: good), administration of medications (self or caregiver), availability of one-dose package, possession of a medication calendar, knowledge about own diagnoses (4-point scale; 4: well known, 1: not known), anxiety about diseases (4-point scale; 4: high, 1: low), intentional noncompliance (4-point scale; 4: intentionally taking none of the prescribed drugs, 3: often deliberately neglecting to take the prescribed drugs (intentional noncompliance, self-selection), 2: occasionally deliberately neglecting to take the prescribed drugs, 1: adhering to the prescribed drugs without any

self-selection), living alone or not, possession of written information about prescribed drugs, number of physicians the patient visited, frequency of visiting a physician, relationship with the physician (4-point scale; 4: very good relationship, 1: very bad), number of prescribed drugs, frequency of drug administration, concern about taking medications (4-point scale; 4: great concern, 1: no concern), and cognitive function.

As we reported in our previous study [21], compliance with prescribed drug regimens was measured by pill counts, which are known to be relatively reliable when performed at the patient's home [30]. All medications found at home were compared with the date of filling the prescription and instructions. The investigator calculated the total number of pills taken correctly. The compliance rate (%) was calculated as the ratio of the total number of pills taken correctly to the total number of pills that should have been taken. A compliance rate below 80% was considered to be poor.

Knowledge about the names, purposes, and dosages of the medication was evaluated by determining the percentage of prescribed drugs that the subjects could tell correctly. Cognitive function was assessed by means of the Mini-Mental State Examination (MMSE) of Folstein et al. [31]. The MMSE is a screening test for dementia, and it is also frequently used to evaluate cognitive impairment in epidemiological studies [32]. It measures several domains of cognitive function, yielding a possible total score ranging from 0 (worst) to 30 (best) points. Cognitive impairment was defined as a score of less than 24 on the MMSE. [33].

Data were analyzed with the two-tailed Student's *t* test for comparisons between independent groups, and the χ^2 test for analysis of the relations between the variables. Linear relations were examined with simple Spearman correlations. Logistic regression analysis was performed to determine the association between the independent variables and the outcome for medication compliance. The following four-point scales were dichotomized for analysis: concern about taking drugs (0: 1 or 2 points, 1: 3 or 4 points), intentional noncompliance (0: 1 or 2 points, 1: 3 or 4 points), poor relationship with a physician (0: 1 or 2 points, 1: 3 or 4 points). Multiple logistic regression analysis was also performed to eliminate the confounding factors. Outcomes with *P* values of less than 0.05 were considered significant. SPSS for Windows, version 8.0J, was used for the analyses.

Results

A total of 223 elderly participated in the study. Three subjects were excluded from the analysis: one could not complete the MMSE, and two were bed-bound; this left 220 subjects for evaluation. The mean age was 75.7 (SD 6.9, range 60–92) years, and 67.7% of the subjects were female. The mean number of prescription drugs taken by an individual at the time of the study was 5.3 (SD 2.9, range 1–18). There were 58 cognitively impaired participants (26.4%) with MMSE scores less than 24, and 76 individuals (34.6%) showed compliance of less than 80%. The characteristics of the subjects and comparison of poor to good compliance are shown in Table 1. Poor compliance was significantly associated with a lower level of education, lower score in MMSE, concern about taking prescribed drugs, intentional noncompliance (self-selection), poor relationship with physicians, lack of one-dose packages, and lack of a medication calendar. The prevalences of the different MMSE scores are shown in Fig. 1.

Table 2 shows the characteristics of the subjects with regard to intact and impaired cognition. The subjects who were cognitively impaired (MMSE \leq 23) were

Table 1 Characteristics of patients and comparison between good and poor compliance

	Good compliance (n = 144)	Poor compliance (n = 76)
Age, years ^a	75.81 (6.94)	75.34 (6.84)
Male ^b	48 (33.3%)	23 (30.3%)
Eyesight ^a	1.29 (0.46)	1.38 (0.54)
Hearing ^a	1.42 (0.56)	1.39 (0.54)
Education level, years ^a	9.47 (2.55)	8.50 (2.70)**
Barthel index ^a	97.60 (9.12)	95.92 (11.96)
Number of drugs ^a	5.15 (2.72)	5.47 (3.14)
Frequency of drug administration ^a	2.78 (1.23)	2.63 (1.13)
Knowledge of diseases ^a	2.88 (0.85)	2.71 (0.85)
Anxiety about diseases ^a	2.15 (1.18)	2.24 (1.23)
Knowledge of drug names, % ^a	6.81 (19.92)	3.94 (14.39)
Knowledge of drug purposes, % ^a	65.70 (34.64)	66.64 (37.54)
Knowledge of drug administration, % ^a	90.56 (25.85)	89.40 (29.06)
MMSE ^a	26.34 (3.29)	25.09 (4.17)*
Concern about taking drugs (3 or 4 points) ^b	14 (9.7%)	21 (27.3%)**
Intentional noncompliance (3 or 4 points) ^b	18 (12.5%)	54 (71.1%***)
Good relationship with a physician (3 or 4 points) ^b	140 (97.2%)	64 (84.2%)**
History of cerebral infarction ^b	38 (26.2%)	22 (28.6%)
One-dose package ^b	23 (16.0%)	5 (6.6%)*
Availability of medication calendar ^b	35 (24.3%)	7 (9.2%)*
Written drug information ^b	125 (86.2%)	61 (79.2%)
MMSE ≤ 23 ^b	31 (21.5%)	27 (35.5%)*
Number of physicians the subject visited ≥ 2 ^b	46 (31.7%)	30 (39.0%)
Self drug administration ^b	137 (95.1%)	71 (93.4%)
Frequency of visiting a physician ≥ once every 2 months ^b	132 (91.7%)	67 (88.2%)

Good compliance, rate of compliance ≥ 80%; Poor compliance, rate of compliance < 80%

MMSE, Mini-Mental State Examination

* $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$; by Student's t test, χ^2 test

^aMean, SD in parenthesis

^bNumber of individuals, percentage of study group in parenthesis

significantly older, were female, had a lower level of education, had less knowledge of medications, and had their drugs administered by caregivers.

Table 3 shows the correlation between variables. Intentional noncompliance was significantly correlated with concern about taking drugs, the number of physicians, a lower frequency of visiting a physician, and a poor relationship with a physician. Concern about taking drugs was associated with anxiety about diseases, a lack of knowledge about drug names, the number of physicians that the patient visits, the number of drugs, the frequency of drug administration, a poor relationship with a physician, and intentional noncompliance. Having a good relationship with a physician was correlated with age, frequency of visiting the physician, absence of intentional noncompliance, the number of drugs, and the frequency of administration.

Logistic regression was performed to determine the association between the independent variables and the outcome of medication compliance. We entered the following variables into the model: age, sex, eyesight poor or not, hearing poor or not, number of drugs, frequency of drug administration, with/without one dose package, with/without medication calendar, with/without written drug information, knowledge of drug name (≥80% or not), knowledge of drug purpose (≥80% or not), knowledge of drug administration (≥80% or not), MMSE (≤ 23 or not), intentional noncompliance (0: 1 or 2 points, 1: 3 or 4 points), concern about taking drugs

(0: 1 or 2 points, 1: 3 or 4 points), poor relationship with a physician (0: 1 or 2 points, 1: 3 or 4 points), less than one visit to a physician every 2 months or not, number of physicians visited, educational level (<8 years or not), and self drug administration or not. In Table 4 we show the significant variables for poor compliance by a univariate analysis and also the results of multiple regression analysis. From univariate analysis, not having a medication calendar (OR 3.16, 95%, CI 1.33–7.52; OR, odds ratio; CI, confidence interval), cognitive impairment (MMSE ≤ 23; OR 2.01, 95%, CI 1.10–3.71), intentional noncompliance (self-selection) (OR 17.18, 95%, CI 8.53–34.59), concern about taking drugs (OR 3.55, 95%, CI 1.68–7.48), poor relationships with physicians (OR 6.56, 95%, CI 2.04–21.14), and educational level below 8 years (OR 2.29, 95%, CI 1.06–4.94) were independent predictors for poor compliance (rate of compliance < 80%). We used multiple logistic regression analysis to eliminate confounding factors. Multiple logistic regression revealed that intentional noncompliance, cognitive impairment (MMSE ≤ 23), and a poor relationship with a physician were independent predictors for poor compliance, with odds ratios of 19.65, 2.94, and 6.24, respectively.

Discussion

In our previous study [21], we investigated risk factors for poor compliance among elderly cognitively normal

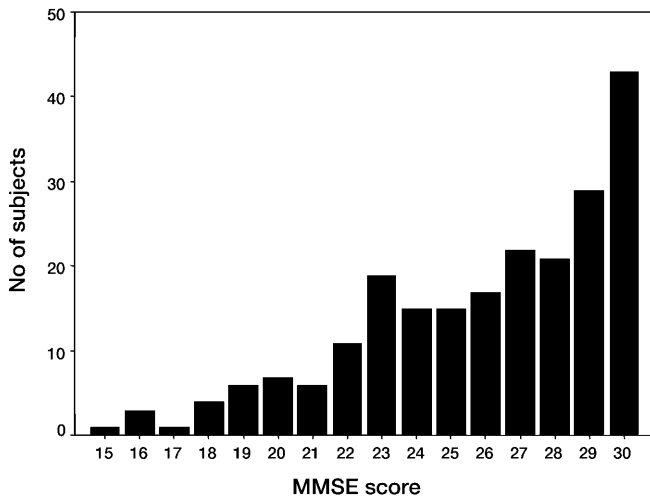


Fig. 1 Distribution of MMSE scores among the study subjects

home-care recipients. During this study, we noticed that there were many elderly individuals with deteriorating cognitive function, who are nevertheless independent in their daily activities. This prompted us to investigate the association between compliance and cognitive impairment. We found that cognitive impairment was one of the predictors for poor compliance. Some other studies failed to find an association between cognitive impairment and noncompliance [9, 28]. Elderly persons with cognitive impairment are conveniently excluded from

most medication compliance research, perhaps because researchers are afraid that these subjects cannot give accurate information for research purposes. In contrast to these studies, for this study we did not exclude the elderly who were independent with regard to their daily activities if they had mild or moderate cognitive impairment as measured by MMSE.

Conn et al. [17] reported no relation between cognitive function and compliance among recently hospitalized elderly patients living in the community who had moderately but not severely impaired cognitive function. Conn and coworkers assumed that these people were receiving assistance from caregivers in the administration of their medication. In our study, the majority (86.2%) of the elderly with cognitive impairment continued to self-manage their medication. The data of the Framingham study [24] showed that there was a graded relation between poorer cognitive performance and the probability of having stopped antihypertensive medication use, and they speculated that cognitive impairment was associated with a reduced adherence to drug treatment regimens. In this study we newly found an association between cognitive impairment and poor compliance with prescribed medication among the elderly functionally independent, including those with mild to moderate cognitive impairment. After we conducted multiple logistic regression analysis, cognitive impairment remained as an independent predictor of poor compliance; however, it is not as strong a predictor as intentional noncompliance. The risk for poor compliance is 2.94

Table 2 Comparison between the cognitively impaired and the cognitively intact ($n = 220$)

	MMSE ≤ 23 ($n = 58$)	MMSE ≥ 24 ($n = 162$)	<i>P</i>
Age in years ^a	78.41 (7.17)	74.66 (6.53)	***
Male ^b	11 (19.0%)	60 (37.0%)	*
Education level in years ^a	7.91 (2.81)	9.57 (2.43)	***
Barthel index ^a	95.26 (12.48)	97.65 (9.21)	ns
Number of drugs ^a	5.52 (2.72)	5.17 (2.92)	ns
Frequency of drug administration ^a	2.71 (1.09)	2.73 (1.24)	ns
Knowledge of disease name ^{a,c}	2.45 (0.82)	2.96 (0.82)	***
Anxiety about disease ^{a,d}	2.29 (1.26)	2.14 (1.17)	ns
Knowledge of drug name, % ^a	2.10 (8.58)	7.15 (20.46)	*
Knowledge of drug purpose, % ^a	49.32 (40.05)	72.01 (31.91)	***
Knowledge of drug administration, % ^a	77.40 (39.60)	94.73 (18.78)	**
MMSE ^a	20.88 (2.22)	27.72 (2.01)	***
Concern about taking drugs (3 or 4 points) ^{b,e}	10 (17.2%)	25 (15.4%)	ns
Intentional noncompliance (3 or 4 points) ^{b,f}	19 (32.8%)	53 (32.7%)	ns
Good relationship with a physician (3 or 4 points) ^{b,g}	53 (91.4%)	151 (93.2%)	ns
History of cerebral infarction ^b	19 (32.8%)	40 (24.7%)	ns
One-dose package ^b	10 (17.2%)	18 (11.1%)	ns
Availability of medication calendar ^b	9 (15.5%)	33 (20.4%)	ns
Written drug information ^b	49 (84.5%)	136 (84.0%)	ns
Number of physicians the subjects visited ≥ 2 ^b	19 (32.8%)	57 (35.2%)	ns
Self drug administration ^b	50 (86.2%)	158 (96.3%)	**
Frequency of visiting a physician \geq once every 2 months ^b	50 (86.2%)	150 (91.5%)	ns
Compliance $< 80\%$ ^b	27 (46.6%)	49 (30.2%)	*

MMSE ≤ 23 , cognitively impaired; MMSE ≥ 24 , cognitively intact
* $P < 0.05$; ** $P < 0.01$; *** $P < 0.0001$; ns, not significant by unpaired t test or χ^2 test

^aMean, SD in parenthesis

^bNumber of individuals, percentage of study group in parenthesis

^cKnowledge of disease name: 4-point scale; 4: well known, 1: not known

^dAnxiety about disease: 4-point scale; 4: great anxiety, 1: no anxiety

^eConcern about taking drugs: 4-point scale; 4: very concerned, 1: no concern

^fIntentional noncompliance: 4-point scale; 4: complete self-selection, 1: no self-selection

^gRelationship with a physician: 4-point scale; 4: good relationship, 1: poor relationship

Table 3 Correlation among variables

Variables	Rate of compliance ^a		Intentional noncompliance ^b		Concern about drugs ^c		Relationship with a physician ^d		MMSE points	
	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>
Rate of compliance, %	–	–	–0.65	***	–0.26	***	0.27	***	0.12	#
Intentional noncompliance	–0.65	***	–	–	0.25	***	–0.30	***	–0.01	ns
Concern about taking drugs	–0.26	***	0.25	***	–	–	–0.28	***	–0.06	ns
Relationship with a physician	0.27	***	–0.30	***	–0.28	***	–	–	–0.04	ns
MMSE	0.12	#	–0.01	ns	–0.06	ns	–0.04	ns	–	–
Age, years	–0.01	ns	0.03	ns	0.00	ns	0.15	*	–0.18	**
Education level, years	0.15	#	–0.06	ns	0.05	ns	0.02	ns	0.38	***
Knowledge of disease names	0.05	ns	0.02	ns	–0.01	ns	0.10	ns	0.29	***
Anxiety about diseases	–0.06	ns	0.01	ns	0.18	**	–0.05	ns	–0.03	ns
Knowledge of drug names	0.05	ns	0.01	ns	0.15	*	–0.04	ns	0.19	**
Knowledge of drug purposes	–0.05	ns	0.12	#	–0.01	ns	–0.16	*	0.2	**
Knowledge of drug administration	–0.04	ns	0.08	ns	–0.05	ns	0.00	ns	0.26	***
Number of drugs	–0.08	ns	–0.05	ns	0.15	*	0.19	**	–0.03	ns
Frequency of drug administration	–0.03	ns	–0.02	ns	0.12	#	0.19	**	–0.01	ns
Number of physicians	–0.18	**	0.14	*	0.15	*	–0.10	ns	0.01	ns
Frequency of visiting a physician/month	0.20	**	–0.19	**	–0.05	ns	0.24	***	0.06	ns

* $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$; # $P < 0.1$; ns, not significant; by Spearman rank correlation

^aRate of compliance (%): number of actually taken prescribed drugs \times 100/total number of prescribed drugs

^bIntentional noncompliance: 4-point scale; 4: complete self-selection, 1: no self-selection

^cConcern about the prescribed drugs: 4-point scale; 4: very concerned, 1: no concern

^dRelationship with a physician: 4-point scale; 4: good relationship, 1: poor relationship

times greater in cognitively impaired (MMSE \leq 23) elderly subjects than in cognitively intact (MMSE 24 or more) individuals. We must assist the elderly in taking their prescribed medication by providing support to compensate for the effects of cognitive impairment.

In addition, we found that intentional noncompliance was the strongest significant predictor for poor compliance. Cooper et al. [14] studied intentional noncompliance and found that patients discontinue or decrease their dosage when experiencing an adverse reaction, and discontinue medication when they experience undesirable outcomes. In our study, the elderly who intentionally neglected to take their prescribed medication (intentional noncompliance, self-selection) tended to have a poor relationship with their physician and are concerned about prescribed drugs.

Compliance has been shown to be highly dependent on communication between patient and health care provider, as shown in our previous study [21, 34]. The present data also suggest that if an elderly person has a good rela-

tionship with the physician, intentional noncompliance and concern about medications may decrease, and compliance may improve. Therefore, health care providers must establish good communication with patients, and provide appropriate information and carefully selected prescriptions, suited to the subject's lifestyle [21, 35].

The relationship between knowledge of medication and the rate of compliance is controversial [21, 35, 36, 37, 38]. We found no relation between knowledge of medication and compliance with taking prescribed drugs. We did find a relation between knowledge of drugs and cognitive function as well as between knowledge of drugs and intentional noncompliance, which were positively correlated. We reported in the previous study that there was a positive relation between knowledge of drugs and compliance in members of a group counseled by a pharmacist; however, there was an inverse relation between knowledge of drugs and compliance in the members of the group that was not counseled by a pharmacist [21]. Williford et al. [22] reported in an intervention study that

Table 4 Analysis by logistic regression ($n = 220$) of factors influencing poor compliance

Variables	Univariate analysis			Multiple logistic regression analysis ^a		
	Odds ratio	95% CI	<i>P</i>	Odds ratio	95% CI	<i>P</i>
Without medication calendar	3.16	1.33–7.52	**			
Education level < 8 years	2.29	1.06–4.94	*			
Concern about taking drugs	3.55	1.68–7.48	***			
Cognitive impairment (MMSE \leq 23)	2.01	1.10–3.71	*	2.94	1.32–6.58	**
Intentional noncompliance	17.18	8.53–34.59	***	19.65	9.22–41.92	***
Poor relationship with a physician	6.56	2.04–21.14	**	6.24	1.55–25.20	**

CI, confidence interval

* $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$

^aSee text for variables entered into the model

discharge counseling by a pharmacist increased both medication knowledge and compliance for patients. These data suggest that sufficient, appropriate drug information by specialists is essential to prevent intentional noncompliance and to decrease poor compliance.

This study revealed that intentional noncompliance, cognitive impairment, and a poor patient–physician relationship are independent predictors for poor compliance with prescribed medication among Japanese elderly aged 60 years and over who are functionally independent and have mild to moderate cognitive impairment. We found that cognitive impairment is one of the predictors for poor compliance; however, it is not as strong a predictor as intentional noncompliance. Intentional noncompliance is the strongest factor for noncompliance and is associated with a poor relationship with the physician, concern about prescribed medication, and inappropriate knowledge of the drugs' purposes. There will be more and more cognitively impaired elderly who self-manage their prescribed drugs. We, medical care providers, should prevent non-compliance by establishing good communication with the elderly, by collecting information about their situations, and by prescribing medication carefully to fit the subjects' lifestyles. Support systems to manage prescribed medication for the cognitively impaired elderly are needed.

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