Original Article

Modification and evaluation of tools for pharmaceutical care of patients with schizophrenia in non-psychiatric hospitals

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Abstract

Nowadays, the hospital pharmacists in Thailand still lack the tools for pharmaceutical care of patients with schizophrenia. The objectives of this study were to modify and evaluate four tools for the care of schizophrenic patients. The Pharmacy Mental Status Examination, the Modified Simpson Angus Scale, the Modified Barnes Akathisia Rating Scale, and the Modified Abnormal Involuntary Movement Scale were modified from the original tools by selecting the items related to the context of pharmaceutical care provided by hospital pharmacists. The evaluation methods were also modified. All of them were modified by two experienced psychiatrists and one experienced pharmacist. A total of 156 volunteer patients were involved in the evaluation of the modified tools. The results showed that all tools had acceptable content validity and internal consistency using the item-objective congruence index and Cronbach's alpha coefficient, respectively. The concurrent validity represented by Spearman rho values indicated that all tools had a strong relationship with the original tools. The inter-rater reliability represented by quadratic-weighted kappa values showed at least good agreement between the experienced psychiatrist and pharmacist. It can be concluded that all modified tools had good validity and reliability and would be useful for routine work of hospital pharmacists in non-psychiatric hospital settings.

Keywords: pharmaceutical care tools, schizophrenia, antipsychotic medications, extrapyramidal symptoms

1. Introduction

Schizophrenia is a chronic and severe mental disorder that affects a patient's perceptions, thoughts, mood, behavior, and interpersonal relationships. The common symptoms of schizophrenia include delusion, hallucination, thought disorders, and movement disorders (The National Institute of Mental Health [NIMH], 2016). The prevalence of schizophrenia in the Thai population was approximately 500,000 people (Phanthunane *et al.,* 2010). Most of them need to be treated with antipsychotic medications for at least two years to control the symptoms and prevent relapse (Lortrakul, 2012).

Normally, patients with schizophrenia will receive treatment in a psychiatric hospital at the initial state before referring them back to a community hospital to continue their treatment to prevent a relapse of symptoms. Pharmaceutical care should be provided to patients during their stay in the community hospitals to prevent and solve drug related problems. The effectiveness and adverse reactions of the antipsychotic medications need to be continuously assessed throughout the treatment. However, most healthcare pro-

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fessionals in the non-psychiatric community hospitals lack specific knowledge on antipsychotic medications. Therefore, the psychotic symptoms and the most common adverse reactions of typical antipsychotic medications and extrapyramidal symptoms (Lortrakul *et al.,* 2012) are not assessed. This problem leads to patient nonadherence to the medication which results in the relapse of symptoms. Finally, these patients have to return to a psychiatric hospital to receive treatment again.

Therefore, pharmaceutical care is helpful for the safety and effectiveness of antipsychotic medications (van Mil *et al.,* 2013). In addition, the number of drug related problems can be reduced along with an increase in the knowledge of schizophrenia, adherence to antipsychotic use, and quality of life in the physical and mental domains (Kanjanasilp *et al.,* 2016). However, hospital pharmacists in Thailand lack the tools for pharmaceutical care of patients with schizophrenia, such as tools to assess antipsychotic treatments in both adverse reactions and effectiveness. Although a direct face-to-face interview is the primary tool that psychiatrists use to assess psychiatric patients, structured interviews, standardized data forms, questionnaires, and rating scales can also be useful tools for the diagnosis and evaluation of treatment outcomes (Work Group on Psychiatric Evaluation, 2006).

Psychiatric assessment tools may help the interviewer create complete structured questions and receive information on all issues within a determined period of time. However, the available tools for assessment thus far are the Positive and Negative Syndrome Scale Thai version (PANSS-T) (Nilchaikovit *et al.,* 2000), the Psychogenic Movement Disorders Scale (Hinson *et al.,* 2005), the Simpson-Angus Scale (SAS) (Simpson *et al.,* 1970), and the Abnormal Involuntary Movement Scale (AIMS) (Guy, 1976). However, since these tools require a long time to interview and evaluate the patients, they are used mostly in research and not for routine work. This study aims to modify and evaluate the tools for use by pharmacists in their routine practice in the pharmaceutical care of patients with schizophrenia in non-psychiatric hospitals.

2. Materials and Methods

2.1 Modification of tools for pharmaceutical care of patients with schizophrenia

Four tools were modified in this study: the Pharmacy Mental Status Examination (PMSE), the Modified Simpson-Angus Scale (Mod-SAS), the Modified Barnes Akathisia Rating Scale (Mod-BARS), and the Modified Abnormal Involuntary Movement Scale (Mod-AIMS). The PMSE was modified for the pharmacists in non-psychiatric hospitals to use for the evaluation of the effectiveness of antipsychotic treatment in all schizophrenic patients who receive medication counseling or acute care service. If the patient develops movement disorders during antipsychotic treatment, the Mod-SAS, the Mod-BARS, and the Mod-AIMS were used to monitor parkinsonism, akathisia, and tardive dyskinesia, respectively.

All of these tools were modified by two psychiatrists who had experience in the treatment of patients with schizophrenia for more than five years and a pharmacist who had experience in pharmaceutical care of patients with schizophrenia for more than five years and was also trained for the interview and assessment of psychiatric symptoms using the Mental Status Examination (MSE) by an expert psychiatrist. The items related to the context of pharmaceutical care performed by hospital pharmacists were selected and included in the modified tools. The PMSE, the Mod-SAS, the Mod-BARS, and the Mod-AIMS were modified from the MSE Thai version (MSE-T) of Suanprung Psychiatric Hospital (Tiam-Kaew, 2012), the SAS, the Barnes Akathisia Rating Scale (BARS) (Barnes, 1989), and the AIMS, respectively. The original tools were translated into the Thai language using common and well-known vocabulary to allow the practical use of these tools. The description of each item was defined including the basis for rating. This study was conducted at Suanprung Psychiatric Hospital, Chiang Mai, Thailand.

2.2 Evaluation of the tools

2.2.1 Volunteers

The inclusion criteria were patients aged 14–80 years, known case with a history of schizophrenia for 4 weeks or longer, on International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD-10), code F 20.x, and duration of the treatment at least 1 day with both typical and atypical antipsychotics. Patients who could not communicate in the Thai language or patients who were threatened with serious medical conditions were excluded from the study. A total of 156 patients were recruited into the study. All patients or their legal representatives (if any) signed the informed consent form. This study was approved by the Suanprung Psychiatric Hospital Ethic Committee.

2.2.2 Content validity

The content validity is the degree to which the elements of an assessment tool are relevant and represent the target, and each tool is built for a particular assessment purpose. The three experts were requested to approve the content validity of the tools with the congruence form. The level of content validity was identified by item-objective congruence index (IOC). A value of IOC near 1.0 shows high content validity and a value less than 0.5 might indicate the need to improve the scale content (Rovinelli *et al.,* 1977).

2.2.3 Internal consistency

Internal consistency is expressed by the Cronbach alpha coefficient (Tang *et al.,* 2014). A total of 22 patients were needed for internal consistency calculated by 90% power, minimum acceptable reliability of 0.6, and minimum desirable reliability of 0.8 (Conroy, 2015).

2.2.4 Concurrent validity

Concurrent validity expresses the degree to which the scores on the test were related to the scores on another established, test administered at the same time. Concurrent validity was presented by the nonparametric version of Pearson's correlation coefficient and Spearman's rank-order correlation coefficient. At 90% power and $\alpha = 0.05$, a total of 25 patients were needed for concurrent validity test (Hulley *et al.,* 2013).

2.2.5 Inter-rater reliability

The inter-rater reliability, the degree of agreement among raters, was expressed as quadratic-weighted kappa (k_w). This study anticipated that raters will agree in about 70% of the gold standard with an expected relative error of 30%. Therefore, 23 patients were needed for the inter-rater reliability (Gwet, 2008).

2.2.6 Data analysis

All statistical analyses were carried out using STATA for Windows version 14.0 (StataCorp LP, College Station, TX, USA).

3. Results

3.1 Modification of tools for pharmaceutical care of patients with schizophrenia

3.1.1 Pharmacy Mental Status Examination (PMSE)

The PMSE was a tool modified from the MSE-T which is used officially by psychiatrists to examine the mental status of patients. It is composed of 15 items used for the assessment. Some items which take a long time in the evaluation and are not relevant to the efficacy of the drug were excluded from the modified tool. These items were consciousness, attention and concentration, memory, and judgment. Therefore, only 11 items were included in the modified tool: 1. general appearance, 2. attitude, 3. psychomotor, 4. affect, 5. mood, 6. speech, 7. thought process, 8. thought content, 9. perception, 10. orientation, and 11. insight. To evaluate the outcome, the severity level of the symptoms was classified as 0 = normal, 1 = minimal symptoms which did not affect the patient's daily life, 2 = symptoms which sometimes affect or have little affect a the patient's daily life, and 3 = symptoms which strongly affect the patient's daily life. It took about 10 minutes to complete the evaluation.

3.1.2 Modified Simpson Angus Scale (Mod-SAS)

The Mod-SAS was modified from the SAS, which had 10 items, and was used to evaluate pseudoparkinsonism. Four items were discarded during the development stage. Two of them, which were shoulder shaking and glabella tap, were discarded because they were not appropriate for routine evaluation by pharmacists. Another two items, which were leg pendulousness and head dropping, were discarded because they required additional equipment and place, such as a bed and table. Therefore, six items were selected for the Mod-SAS: 1. gait, 2. arm dropping, 3. elbow rigidity, 4. wrist rigidity, 5. tremor, and 6. salivation. Each item had 5 levels of severity (0–4). The evaluation was modified from the original one (Hawley *et al.,* 2003). It considered the score of individual items which was evaluated in four levels. A score of 0 meant normal. A score of 1 meant the patient should be monitored weekly by the pharmacist (mild symptoms). A score of 2 meant the pharmacist should consult a doctor to consider a revision of the treatment plan (moderate symptoms). A score of 3 to 4 means the pharmacist should consult the doctor immediately to consider treatment (severe symptoms). If the score of the evaluation was 1 or more, the patient should be monitored and evaluated for pseudoparkinsonism. It took about 5 minutes for the evaluation.

3.1.3 Modified Barnes Akathisia Rating Scale (Mod-BARS)

The Mod-BARS was modified from the BARS, which is widely used in clinical studies to evaluate motor restlessness syndrome caused by antipsychotics. The four main items of BARS are 1. objective, 2. subjective (awareness of restlessness), 3. subjective (distress related to restlessness), and 4. global clinical assessment of akathisia. They were chosen for the Mod-BARS where all details of the contents in the tools were preserved. The first three items had 4 levels of severity (0–3), and the fourth item had 6 levels of severity (0–5). The evaluation of the Mod-BARS was modified from the original one. If the evaluation score of the global clinical assessment of akathisia was 1 or more, the symptom should be monitored for akathisia by the pharmacist. The evaluation took 5 minutes to complete.

3.1.4 Modified Abnormal Involuntary Movement Scale (Mod-AIMS)

The Mod-AIMS was modified from the AIMS which is used to evaluate the symptoms and severity of choreoathetosis and other movement symptoms of tardive dyskinesia (TD). It consists of 14 items, but two of them were discarded during the modification stage for the conciseness of the tools. Therefore, the Mod-AIMS consisted of 12 topics where 10 of them must rate the movement disorder as 5 levels (0–4). Those 10 items included 1. muscle of facial expression, 2. lips and perioral area, 3. jaw, 4. tongue, 5. upper extremities (arms, wrists, hands, fingers), 6. lower extremities (legs, knees, ankles, toes), 7. neck, shoulders, and hips, 8. severity of abnormal movement overall, 9. incapacitation due to abnormal movements, and 10. patient's awareness of abnormal movements. Another two items were evaluated by yes or no. Those two items were 11. current problems with teeth or dentures or both, and 12. the question "Are dentures usually worn?" The evaluation part was newly modified from the original one (Schooler *et al.,* 1982). It considered the scores of the individual items. If the score from the rating was 1 or more, the patients would be monitored and evaluated for TD. It took 10 minutes to complete the evaluation.

3.2 Evaluation of the tools for pharmaceutical care of schizophrenia patients

The demographics of the patients with schizophrenia who volunteered to participate in this study are shown in Table 1.

3.2.1 Content validity

The content validities of the four modified tools were evaluated by three experienced psychiatrists. The results indicated that every tool had an acceptable content validity or better. This can be observed from the IOC values (Table 2).

Table 1.   Baseline characteristics of the schizophrenic patients who participated in the study.

Patients	PMSE n = 48	Mod-SAS n = 50	Mod-BARS n = 30	Mod-AIMS n = 28	Total N = 156
Male, %	52.1	48.0	56.7	46.4	50.6
Age, years, mean ± SD	42.8 ± 13.4	47.0 ± 15.6	42.9 ± 14.2	57.6 ± 13.5	46.9 ± 15.2
Duration of the illness	≥4 weeks	≥4 weeks	≥4 weeks	≥4 weeks	≥4 weeks
Duration of the treatment	≥1 day	≥1 day	≥1 day	≥1 day	≥1 day

PMSE = Pharmacy Mental Status Examination; Mod-SAS = Modified Simpson Angus Rating Scale; Mod-BARS = Modified Barnes Akathisia Rating Scale; Mod-AIMS = Modified Abnormal Involuntary Movement Scale.

Table 2.   Content validity and internal consistency of the four tools for pharmaceutical care of patients with schizophrenia.

	Number of participants	IOC	Cronbach's alpha
PMSE	24	0.67–1.00	0.853
Mod-SAS	27	1.00	0.801
Mod-BARS	27	0.67–1.00	0.929
Mod-AIMS	27	0.67–1.00	0.731

PMSE = Pharmacy Mental Status Examination; Mod-SAS = Modified Simpson Angus Rating Scale; Mod-BARS = Modified Barnes Akathisia Rating Scale; Mod-AIMS = Modified Abnormal Involuntary Movement Scale.

3.2.2 Internal consistency

The internal consistency of all four modified tools was tested by two experienced pharmacists. The results indicated that all tools had an acceptable internal consistency (Table 2). In the case of the PMSE, which originally had 11 items, it was found that two topics did not correlate very well with the overall items. Since the item-rest correlation of general appearance and speech were 0.159 and 0.144, respectively, they were discarded. Therefore, 9 items remained and the Cronbach's alpha value increased from 0.833 to 0.853.

3.2.3 Concurrent validity

The concurrent validity of all four tools was implemented by two experienced psychiatrists. The patients were evaluated independently by the original tools and the evaluation results were blinded from other assessors. At the same time, two experienced pharmacists evaluated the patients by the newly modified tools. The relationship between the original tools and the newly modified tools was analyzed. The results indicated that all tools had a strong relationship in the positive direction with statistically significance (Table 3).

3.2.4 Inter-rater reliability

The inter-rater reliability was implemented by allowing an experienced psychiatrist to interview the patients and the interviews were observed by an experienced pharmacist. After finishing interview of each patient, both the psychiatrist and pharmacist independently rated each item in the modified tools. The results of the analysis of the psychiatrist showed good agreement with those of the pharmacist. The PMSE and the Mod-AIMS showed very good agreement, while the Mod-SAS and the Mod-BARS showed good agreement (Table 4).

Table 3.   Concurrent validity of the four tools for pharmaceutical care of patients with schizophrenia.

Modified tools	Compared tools	Direction	Spearman rho	P-value
PMSE	MSE-T	+	$r_s(34) = 0.963$	<0.001
Mod-SAS	SAS	+	$r_s(26) = 0.777$	<0.001
Mod-BARS	BARS	+	$r_s(29) = 0.802$	<0.001
Mod-AIMS	AIMS	+	$r_s(26) = 1.000$	<0.001

PMSE = Pharmacy Mental Status Examination; MSE-T = Mental Status Examination Thai version; Mod-SAS = Modified Simpson Angus Rating Scale; SAS = Simpson-Angus Scale; Mod-BARS = Modified Barnes Akathisia Rating Scale; BARS = Barnes Akathisia Rating Scale; Mod-AIMS = Modified Abnormal Involuntary Movement Scale; AIMS = Abnormal Involuntary Movement Scale.

Table 4.   Agreement of the four tools for pharmaceutical care of patients with schizophrenia.

	Number of participants	Weighted Kappa, quadratic	P-value
PMSE	24	0.976	<0.001
Mod-SAS	23	0.768	<0.001
Mod-BARS	30	0.783	<0.001
Mod-AIMS	23	0.965	<0.001

PMSE = Pharmacy Mental Status Examination; Mod-SAS = Modified Simpson Angus Rating Scale; Mod-BARS = Modified Barnes Akathisia Rating Scale; Mod-AIMS = Modified Abnormal Involuntary Movement Scale

4. Discussion

Four tools were modified from the original tools to correspond with drug use monitoring and evaluation, as well as movement disorder symptoms caused by antipsychotics. Since the purpose of the tools was to monitor symptoms, not for diagnostic purposes, only some evaluation criteria of the original tools were selected.

The results indicated that all four tools had good validity and reliability. In addition, there are many obvious advantages of these tools. First, the items were selected in such

a way that a pharmacist can use them easily. Second, the evaluation results were closely related to those obtained from the original tools. Third, the evaluation by each tool did not take much time. These tools can be helpful for the routine work of pharmacists who work in non-psychiatric hospitals. However, the pharmacists who use these tools need to graduate from a short training course in psychiatric pharmaceutical care for effective use of the tools.

The construct validity of the tools used in this study was not tested. These tools were not newly developed but were modified from the original tools employed by psychiatrists. The target users are non-psychiatric hospital pharmacists who have a significant lower level of psychiatric knowledge and skills compared to the psychiatrists. The construct validity of the modified tools may have changed compared to the original tools because the experts removed some items which were not suitable for the target pharmacists.

This study has limitations. This study did not apply reverse translation by a language expert, but an experienced psychiatrist chose the words that are commonly used for each item of the tools in response to the usage in the psychiatry arena. These tools should be further examined on effectiveness and feasibility in a representative sample. Although the number of patients with schizophrenia participating in this study was low, it was sufficient for the statistical analysis.

5. Conclusions

This study modified and evaluated four tools for pharmaceutical care of patients with schizophrenia. The results indicated that all modified tools had good validity and reliability and can be used in routine work.

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