

Evaluation of Medicine Information Leaflets for Omeprazole, Safety Knowledge, and Perceptions of Taking the Medication in Thailand

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Purpose: This study aimed to compare package inserts and patient information leaflets for omeprazole in terms of the quality of and satisfaction with the written medicine information, medication safety knowledge, and perceived benefits and risks.

Patients and methods: A cross-sectional, comparative study was conducted at a university hospital in Thailand. Outpatients visiting the pharmacy departments prescribed omeprazole were randomly selected to receive either a package insert or a patient information leaflet. Medication safety knowledge was measured using a set of eight questions. The quality of the written medicine information was measured by the Consumer Information Rating Form. Perceived benefits and risks of the medication were rated using a visual analog scale. Linear regression was used to determine factors associated with perceived benefits and risks.

Results: Of the 645 patients, 293 agreed to answer the questionnaire. 157 and 136 patients were given patient information leaflets and package inserts, respectively. Most respondents were female (65.6%), over half had a degree (56.2%). Patients reading the patient information leaflets had slightly higher overall safety knowledge scores than those reading the package inserts (5.88 ± 2.25 vs 5.25 ± 1.84 , $p=0.01$). Using the Consumer Information Rating Form, the patient information leaflets were given significantly higher scores compared to the package inserts for comprehensibility (19.34 ± 3.92 vs 17.32 ± 3.52 , $p<0.001$) and design quality (29.25 ± 5.00 vs 23.81 ± 5.16 , $p<0.001$). After reading the leaflets, patients receiving the patient information leaflets had significantly higher satisfaction with the information provided ($p=0.003$). In contrast, those receiving the package inserts rated the risks of omeprazole higher ($p=0.007$).

Conclusion: Demonstrable differences were found from the patient perspective between a package insert and a patient information leaflet for the same medicine, mostly in favour of patient information leaflets. Medicine safety knowledge after reading PI and PIL was similar. However, receiving package inserts provided higher perceived risks from taking the medicine.

Keywords: written medicine information, safety knowledge, consumer information rating form, perceptions of benefits and risks

Introduction

Medicine information plays an important role in ensuring that patients are able to use their medications correctly and safely. Some patients forget or misunderstand verbal information provided by healthcare professionals. To improve patients' understanding of medicines, written medicines information (WMI) has been widely used as an additional source to support patients' recall.

There are two main types of written medicine leaflets available to patients. Package inserts (PIs) or summaries of product characteristics are aimed at health professionals, but are frequently provided as leaflets in medicine packages, therefore are accessible to patients. Studies show that consumers are aware of and report reading PIs.^{1,2} A study in Thailand also found that PIs were common sources of information regarding medication, and most patients reported reading them, particularly for newly prescribed medications.³ However, most PIs are considered difficult to understand for patients due to the use of complex medical terms and inappropriate format.⁴⁻⁷ Patient information leaflets (PILs) are

another form of WMI produced in simple language and patient-friendly format. Many countries, such as European countries and Australia, promote the development and distribution of PILs as primary information about medicines and support the use of PILs in patient counselling.^{8,9} Studies in many countries have found that patients often have difficulty in understanding the language and technical terms used in WMI and that level of education is associated with both reading WMI and medication knowledge.^{10–12} Studies in Thailand in patients using chronic medications showed that they had positive attitudes toward receiving information about medicines safety,¹³ and did not have anxiety after reading the side effect information in PILs.¹⁴

Before distributing to consumers, PILs need to be evaluated using consumer involvement for ease of reading, understanding, and communicative effectiveness.¹⁵ Several methods for evaluating these have been studied, covering several dimensions, including understandability, format, readability, satisfaction with information, utility, and actionability.¹⁶ The Consumer Information Rating Form (CIRF) was developed originally in English to measure consumers' perceptions of the comprehensibility, utility, and design quality of written medicine information.^{17,18} It has been translated and demonstrated feasible for use in other languages.^{19,20} Previous studies evaluating WMI in Thailand showed that the CIRF could be practically used to assess consumers' comprehension and the usefulness of written information for chronic medications.^{20,21}

Relatively little research has sought patients' views on different forms of WMI using standardized methods,²¹ but given the widespread provision of PIs to patients, is essential to determine whether PILs would offer a better alternative.

In this study, we, therefore, compared patient views on two different forms of WMI, PIs and PILs, for the same medicine. Omeprazole, a proton-pump inhibitor, was chosen as it can be used short or long-term. It is widely prescribed short-term for treating several conditions, including peptic ulcer disease, gastrointestinal reflux disease, and helicobacter pylori infection. It is also prescribed long-term for secondary prevention of gastric ulcers in patients receiving non-steroidal anti-inflammatory drugs.^{22–25} However, studies have reported gastrointestinal side effects including constipation due to PPI use²⁶ and long-term use of PPIs can potentially cause significant adverse effects, including chronic kidney disease, pneumonia, hypomagnesemia, vitamin B12 deficiency, and *Clostridium difficile* infection.^{22,27}

Our aim was to compare hospital outpatients' ratings of the quality of PIs and PILs for omeprazole and to assess their safety knowledge of and perceived benefits and risks of this medicine.

Methods

Study Design and Settings

This was a cross-sectional, comparative study using a self-completed questionnaire performed in the outpatient clinic of Srinagarind Hospital, Khon Kaen University, Thailand, carried out over a three-month period.

Participants

Outpatients aged 18 years old or more and prescribed omeprazole as one of their medications were recruited to the study at the hospital pharmacy department. Participants were excluded from the study if they could not read the written information written provided in the study, were unable to complete the questionnaire themselves or with caregivers' support and had ever previously assessed the quality of WMI prior to the study. The sample size was calculated to investigate a comparison of patients' knowledge received from the PI and PIL²⁸ as follows.

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 (\pi_1(1-\pi_1) + \pi_2(1-\pi_2))}{(\pi_1 - \pi_2)^2}$$

Where π_1 = patients' knowledge received from PI (59%) based on Patterson and Teale's study²⁹

π_2 = patients' knowledge received from PIL (0.75%) based on Jarernsiripornkul et al's study.³⁰

Since the difference in knowledge received from PI and PIL was 16% (0.16) with alpha error at 5%, and power of the study (beta) at 80%, a total of 300 participants was calculated to obtain enough sample size (each 150 patients in the PI and PIL group).

Study Instruments

Questionnaire

The self-administered questionnaire consisted of three sections. The first section was demographic characteristics of the participants, including gender, age, educational level, income, occupation, number of underlying diseases and prescribed medications, and experience of receiving PI or PIL for omeprazole prior to the study. The second section was the evaluation of written information on omeprazole using the Consumer Information Rating Form (CIRF). The CIRF consists of 4 components that evaluate the quality of WMI: comprehensibility, future use of WMI, utility, and design. The comprehensibility component covers five items on how easy or hard the WMI is to read, understand, remember, locate information, and keep the information for future reference. The future use component contains three items on the likelihood of WMI to read, use, and keep. The utility component has six items of how much information is provided in the WMI and how useful it is. The design component consists of seven items on perceptions about the organization, attractiveness, print size, tone, helpfulness, bias, and spacing between lines.¹⁷ The acceptable validity and reliability of a Thai version of the CIRF were also demonstrated.²⁰

The third section was the assessment of safety knowledge of omeprazole use using eight questions with multiple choices covering how to take medicine (1 item), administration (1 item), adverse effects (2 items), overdosage (1 item), contraindication (1 item), precaution (item), and what to do when the dose was missed (1 item). The fourth section contained six items that were summarized into three components: satisfaction of information in the PI or PIL, perceptions of benefits and risks of taking medicine after reading the PI and PIL using a visual analog scale (VAS).

Written Information Leaflets

Two different forms of WMI were used in the study. The first was a PI from an omeprazole package produced by the manufacturer. This two-page PI contained information on the indication, the general appearance of the medicine product, the active ingredient, dosage recommendations, pharmacodynamics, pharmacokinetics, contraindications, precautions, drug interactions, adverse effects, overdosage management, storage, use in pregnancy and lactation. The information was written as descriptive text, and categorized into topics. Some medical terms were used.

The second was a one-page PIL developed by the Thai Food and Drug Administration (FDA). The PIL contained six main topics regarding what is the medicine and what is it used for; precautions before using the medicine; how to take the medicine; things to do while using the medicine; possible side effects; and how to store the medicine. The information was written in short sentences, with headings and subheadings to help patients read and find the information easily. Simple language was used, and medical terms were avoided. User testing was used to ensure that readers could read and understand the information.

Data Collection

After patients had received their medicines, the questionnaire together with a cover page explaining the study was directly distributed to the outpatients by researchers trained to ensure consistency in approach. Each participant who was willing to take part in the study received an explanation of the study's objectives. They were randomly assigned to receive either a copy of the PI or PIL for omeprazole using permuted block technique. Those who agreed were asked to read the leaflet provided carefully and then complete the questionnaire. The questionnaires were returned directly to the researchers after completion.

Data Analysis

Data analyses were performed using IBM SPSS version 25.0. Descriptive characteristics were summarized as frequencies. The CIRF responses were summarized as total scores; perceptions of benefits and risks of taking medicines were presented as VAS scores ranging from 0 (least) to 10 (most); safety knowledge was summed by allocating one point for each correct answer (total score=8). Medicine safety knowledge scores were summed and classified into three categories: poor (percentage of correct answers less than 50% or less than 4 of 8 points), moderate (percentage of correct answers 50–80% or 4–6 points), and good (percentage of correct answers more than 80% or more than 6 of 8 points).

Independent *t*-tests and one-way ANOVA were used to compare subgroups for the CIRF and perception scores between the PI and PIL groups. Pearson chi-square or Fisher's exact test was used to compare subgroups for categorical data. Linear regression was used to determine factors associated with the perceptions of benefits and risks of taking the medicines after reading the PI and PIL. After applying the Bonferroni adjustment, results with a *p*-value less than 0.0006 were considered statistically significant.

Ethical Approval

The study protocol was approved by the Khon Kaen University Ethics Committee for Human Research (HE611500) and conducted in accordance with the Declaration of Helsinki. All participants provided verbal informed consent before joining the study. The Khon Kaen University Ethics Committee approved verbal informed consent from study participants.

Results

Demographic Characteristics of Patients

A total of 645 outpatients were verbally invited by the researchers, of which 347 (53.8%) refused to participate. Five of the returned questionnaires were completed with less than 70% of all items, so were excluded from analysis. Hence, 293 questionnaires were analyzed, giving an overall response rate of 45.4%. Around two-thirds of participants (*n* = 191, 65.6%) were female, and 59.4% (*n* = 174) were aged 30–60. More than half had educational levels at a bachelor's degree or higher (*n* = 164, 56.2%). The majority of respondents had never received any form of written information about omeprazole (*n* = 197, 67.5%). Table 1 describes the characteristics of 157 patients who received the PI and 136 who received the PIL. Respondents in the PIL group were likely to be slightly older and had a greater number of underlying diseases and medications than those in the PI group (*p*<0.001, *p*=0.001, and *p*<0.001).

Quality Evaluation of the Written Medicine Information

A comparison of the CIRF scores between respondents reading PI and PIL is presented in Table 2. For overall scores, PILs were rated higher than PI for comprehensibility (mean difference, MD = 2.02), future use (MD = 1.01), and design quality (MD = 5.44) (*p*<0.0006). No significant differences in any aspects of the utility component, which included contraindications, precautions, adverse effects, and special instructions were found between the PI and PIL groups.

Assessment of Safety Knowledge of Omeprazole Use

The question about how to take medicine was answered correctly by almost all respondents in both the PI and PIL groups (96.2% and 94.9%), while the question about serious adverse effects achieved the least correct response (24.8% for the PI group and 53.7% for the PIL group). While the average score of safety knowledge about omeprazole for the PIL group was slightly higher than the PI group (5.88 ± 2.252 and 5.25 ± 1.835 , *p*=0.01), only one question showed a significantly higher proportion of correct scores in the PIL group compared to the PI group, relating to side effects requiring cessation of treatment (53.7% vs 24.8%, *p*<0.001) (Table 3). Around half of the PI group had moderate safety knowledge, while half of the PIL group had good safety knowledge. Patients in the PIL group were likely to show higher levels of safety knowledge, but there was no statistically significant difference between the two groups (Table 4).

Perceived Satisfaction, Benefits and Risks

Respondents in the PIL group had a significantly higher score for satisfaction with information than in the PI group (7.64 ± 2.057 and 6.92 ± 2.087 , *p* = 0.003). For the risks associated with taking omeprazole, perceptions were higher in those receiving the PI compared to the PIL (14.43 ± 5.304 and 12.67 ± 5.837 , *p*=0.007) (Figure 1). However, no significant difference in benefit perceptions was observed between the two groups. Multiple linear regression showed no statistically significant differences between reading PIs and PILs in perceptions, however type of material was the factor most highly associated with all three aspects (Table 5).

Table I Demographic Characteristics of Patients Receiving PI and PIL

Characteristics	Type of Information Material (n, %)		Total (n, %) (n = 293)	p-value ^b
	PI (n, %) (n = 157)	PIL (n, %) (n = 136)		
Gender				
Male	49 (31.6)	51 (37.5)	100 (34.4)	0.291
Female	106 (68.4)	85 (62.5)	191 (65.6)	
Age group (years)				
< 30	14 (8.9)	2 (1.5)	16 (5.5)	<0.001
30–60	100 (63.7)	74 (54.4)	174 (59.4)	
> 60	43 (27.4)	60 (44.1)	103 (35.2)	
Educational level				
< Bachelor's degree	69 (43.9)	59 (43.7)	128 (43.8)	0.966
≥ Bachelor's degree	88 (56.1)	76 (56.3)	164 (56.2)	
Occupation				
Agriculture	29 (18.5)	25 (18.4)	54 (18.4)	0.376
Civil servant	59 (37.5)	65 (47.8)	124 (42.3)	
Employee	13 (8.3)	7 (5.2)	20 (6.9)	
Own business	27 (17.2)	21 (15.4)	48 (16.4)	
Unemployed/student/others ^a	29 (18.5)	18 (13.2)	47 (16.0)	
Income per month (baht)				
≤ 10,000	58 (36.9)	43 (32.8)	101 (35.1)	0.253
10,001–30,000	58 (36.9)	42 (32.1)	100 (34.7)	
> 30,000	41 (26.2)	46 (35.1)	87 (30.2)	
Health insurance				
Universal coverage scheme	38 (24.4)	29 (21.3)	67 (22.9)	0.827
Civil servant medical benefit scheme	95 (60.9)	86 (63.2)	181 (62.0)	
Social security scheme/self-pay	23 (14.7)	21 (15.5)	44 (15.1)	
Number of underlying diseases				
None	67 (42.7)	29 (21.3)	96 (32.8)	0.001
1	54 (34.4)	65 (47.8)	119 (40.6)	
≥ 2	36 (22.9)	42 (30.9)	78 (26.6)	
Number of concurrent medications				
None	63 (40.1)	27 (19.9)	90 (30.7)	<0.001
1–3	33 (21.0)	47 (34.6)	80 (27.3)	
≥ 4	61 (38.9)	62 (45.5)	123 (42.0)	
Drug allergy				
No	134 (85.4)	110 (80.9)	244 (83.3)	0.307
Yes	23 (14.6)	26 (19.1)	49 (16.7)	
Reading drug information material prior to the study				
No	105 (67.3)	92 (67.6)	197 (67.5)	0.951
Yes	51 (32.7)	44 (32.4)	95 (32.5)	

Notes: ^aOthers: housewives, monk, freelance. ^bAnalyzed by Pearson's chi-square test. Statistical significance at the $p < 0.05$ with Bonferroni correction ($p < 0.0006$) is shown in bold values.

Abbreviations: PI, Package insert; PIL, Patient information leaflet.

Table 2 Comparison of Patients Rating the Quality of PI and PIL

Items	Rating Scores (Mean $\pm$ S.D.)		Mean Difference	p-value ^a
	PI (n = 157)	PIL (n = 136)		
Comprehensibility				
1. Read	3.25 $\pm$ 0.94	4.05 $\pm$ 0.90	0.80	<0.001
2. Understand	3.58 $\pm$ 0.85	4.01 $\pm$ 0.91	0.43	<0.001
3. Remember	3.25 $\pm$ 0.94	3.66 $\pm$ 0.90	0.41	<0.001
4. Locate	3.48 $\pm$ 0.84	3.57 $\pm$ 0.91	0.09	0.368
5. Keep for future reference	3.71 $\pm$ 0.84	4.04 $\pm$ 0.99	0.33	0.002
Total score	17.32 $\pm$ 3.52	19.34 $\pm$ 3.92	2.02	<0.001
Future use				
1. Read	4.13 $\pm$ 0.99	4.46 $\pm$ 0.82	0.33	0.002
2. Use	4.31 $\pm$ 0.84	4.46 $\pm$ 0.82	0.15	0.126
3. Keep	3.78 $\pm$ 1.21	4.31 $\pm$ 0.85	0.53	<0.001
Total score	12.21 $\pm$ 2.63	13.22 $\pm$ 2.11	1.01	<0.001
Utility				
1. Benefits	3.50 $\pm$ 0.69	3.65 $\pm$ 0.61	0.15	0.039
2. Contraindications	3.30 $\pm$ 0.80	3.24 $\pm$ 0.87	-0.06	0.555
3. Directions	3.42 $\pm$ 0.74	3.51 $\pm$ 0.73	0.09	0.255
4. Precautions	3.49 $\pm$ 0.73	3.45 $\pm$ 0.74	-0.04	0.655
5. Adverse effects	3.34 $\pm$ 0.79	3.39 $\pm$ 0.77	0.05	0.569
6. Storage	3.43 $\pm$ 0.78	3.60 $\pm$ 0.66	0.17	0.048
Total score	20.50 $\pm$ 3.63	20.83 $\pm$ 3.32	0.33	0.429
Design				
1. Organization	4.03 $\pm$ 0.87	4.31 $\pm$ 0.74	0.28	0.004
2. Attractiveness	3.03 $\pm$ 1.12	3.97 $\pm$ 0.88	0.94	<0.001
3. Print size	2.70 $\pm$ 1.14	4.19 $\pm$ 1.01	1.49	<0.001
4. Tone	3.29 $\pm$ 1.05	3.96 $\pm$ 1.09	0.67	<0.001
5. Helpfulness	3.97 $\pm$ 1.15	4.24 $\pm$ 1.07	0.27	0.041
6. Bias	3.70 $\pm$ 1.13	4.19 $\pm$ 0.96	0.49	<0.001
7. Spacing	3.14 $\pm$ 1.19	4.29 $\pm$ 0.96	1.15	<0.001
Total score	23.81 $\pm$ 5.16	29.25 $\pm$ 5.00	5.44	<0.001

Notes: ^aAnalyzed by independent t-test. Statistical significance at the $p < 0.05$ with Bonferroni correction ($p < 0.0006$) is shown in bold values.

Abbreviations: PI, Package insert; PIL, Patient information leaflet.

Table 3 Comparison of Safety Knowledge of Omeprazole Between Reading PI and PIL

Questions	PI (n = 157)		PIL (n = 136)		p-value ^a
	Correct (n, %)	Incorrect (n, %)	Correct (n, %)	Incorrect (n, %)	
1. How to take this medicine	151 (96.2)	6 (3.8)	129 (94.9)	7 (5.1)	0.583
2. What is the correct way to take this medicine	145 (92.4)	12 (7.6)	127 (93.4)	9 (6.6)	0.734
3. Which side effect do you need to stop taking the medicine and see the doctor immediately	39 (24.8)	118 (75.2)	73 (53.7)	63 (46.3)	<0.001
4. Which side effect is not necessary to stop taking this medicine	80 (51.0)	77 (49.0)	83 (61.0)	53 (39.0)	0.083
5. What should you do if you forget to take the drug	116 (73.9)	41 (26.1)	104 (76.5)	32 (23.5)	0.610
6. What would you do if you take this medicine overdose	124 (79.0)	33 (21.0)	108 (79.4)	28 (20.6)	0.928
7. Who is contraindicated to use this medicine	84 (53.5)	73 (46.5)	81 (59.6)	55 (40.4)	0.297
8. Who should be careful when taking this medicine	85 (54.1)	72 (45.9)	94 (69.1)	42 (30.9)	0.009
Total score (mean $\pm$ S.D.)	5.25 $\pm$ 1.84		5.88 $\pm$ 2.25		0.010 ^b

Notes: ^aAnalyzed by Pearson's chi-square test. ^bAnalyzed by independent t-test. Score range from 0 to 8. Statistical significance at the $p < 0.05$ with Bonferroni correction ($p < 0.0006$) is shown in bold values.

Abbreviations: PI, Package insert; PIL, Patient information leaflet.

Table 4 Comparison of Safety Knowledge Level Between Reading PI and PIL

Level of Knowledge	Types of Information Material				Total		p-value ^a
	PI		PIL				
	N (%)	Mean ± S.D.	N (%)	Mean ± S.D.	N (%)	Mean ± S.D.	
Poor knowledge	28 (17.8)	2.32 ± 0.86	25 (18.4)	2.12 ± 0.88	53 (18.1)	2.23 ± 0.87	0.371
Moderate knowledge	86 (54.8)	5.12 ± 0.77	37 (27.2)	4.83 ± 0.76	123 (42.0)	5.03 ± 0.78	0.188
Good knowledge	43 (27.4)	7.41±0.50	74 (54.4)	7.66 ± 0.48	117 (39.9)	7.57 ± 0.50	0.010

Notes: ^aAnalyzed by Pearson's chi-square test. Poor knowledge: percentage of correct answers less than 50% (< 4 points), Medium knowledge = 50 to 80% (≥ 4 to 6 points), Good knowledge = more than 80% (> 6 to 8 points). $p < 0.05$ with Bonferroni correction ($p < 0.0006$) was considered statistically significant.

Abbreviations: PI, Package insert; PIL, Patient information leaflet.

Discussion

This study describes patients' evaluation of two different forms of WMI and compares medication safety knowledge, perceived benefits and risks and satisfaction with information. PILs were rated superior to the PIs for comprehensibility, future use of information, design and satisfaction, but the content was rated similarly for utility and both safety knowledge and perceived benefits were similar in both groups. Risks were perceived as higher in those receiving PIs.

Our respondents rated PIs and PILs similarly in terms of the utility of their content, despite the information in PIs being more lengthy and complex. This finding differs from our previous study in which all aspects of utility were rated higher by those receiving PILs for medicines used long-term compared to PIs.²¹ The group receiving PIs were younger, had fewer underlying conditions and therefore used fewer regular medicines than those receiving PILs. It is possible that those receiving the PIL had therefore been exposed to more information about medicine safety in general and omeprazole in particular. Both groups had similarly high education levels and reported previous experience with WMI, factors which have been shown to affect reading and understanding of WMI.^{31,32} Overall, respondents were slightly younger than in our previous study, and age has been shown to affect views on information.^{32–34}

Safety knowledge, assessed by eight questions, was also similar in the two groups, with the exception of symptoms requiring stopping therapy, which was answered more correctly by receiving a PIL. However, the risks associated with the medicine were perceived as higher in those receiving PIs. One possible reason for these differences is the presentation of adverse effect information in the two documents. In the PI, all possible adverse effects were listed together, whereas in the PIL serious and non-serious effects were separated and the language differed. In addition, since PIs are aimed at health professionals, they frequently do not offer advice on what to do if symptoms occur.³⁵ Benefit of reading PIL was demonstrated in a pre-post study in Thailand in which patients had more knowledge about taking atorvastatin after reading the PIL.¹⁴ A survey in Thailand found that consumers did not want to read the PIs because of difficult content and small print.³⁶ After being promoted by the Thai FDA, the consumers were more aware of and need to read the

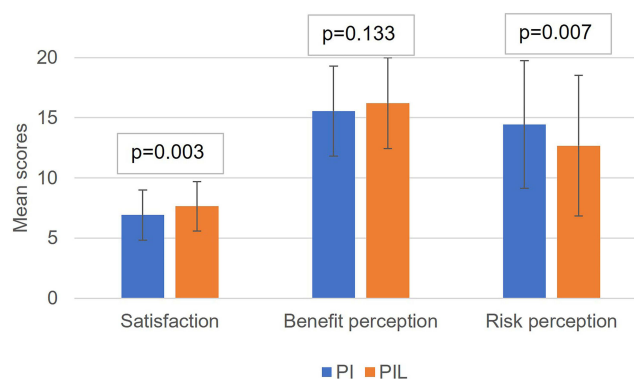
**Figure 1** Comparison of satisfaction of information, perceived benefits and risks from taking the medicine between reading PI and PIL.

Table 5 Linear Regression for Satisfaction of Information, Perceived Benefits and Risks from Taking the Medicine

Factors	b	SE _b	β	t	95% CI		p-value
					Lower	Upper	
Satisfaction with information ^a							
Type of material – PIL	0.639	0.247	0.151	2.591	0.153	1.125	0.010
Income per month (baht)							
10,001–30,000	0.601	0.301	0.136	2.000	0.010	1.193	0.046
> 30,000	0.783	0.327	0.171	2.396	0.140	1.426	0.017
Health insurance							
Social security scheme/ self-pay	−0.920	0.415	−0.156	−2.218	−1.736	−0.104	0.027
Civil servant medical benefit scheme	−0.236	0.324	−0.054	−0.728	−0.874	0.402	0.467
	Constant 6.639; SE _{est} = ±2.0464 R = 0.274; Adjusted R ² = 0.055; F=0.039; p-value=0.843						
Perceived benefits from taking the medicine ^b							
Type of material – PIL	1.027	0.443	0.135	2.318	0.155	1.900	0.021
	Constant 15.070; SE _{est} = ±3.7389 R=0.159; Adjusted R ² = 0.015; F=2.483; p-value=0.061						
Perceived risks from taking the medicine ^c							
Type of material – PIL	−1.848	0.677	−0.163	−2.732	−3.180	−0.516	0.007
	Constant 14.429; SE _{est} = ±5.6409 R=0.201; Adjusted R ² = 0.009; F=1.292; p-value= 0.241						

Notes: b denotes the variable estimate, SE_b denotes the standard error of the variable estimate, β denotes the standardized estimate. ^aAdjusted for type of materials, educational level, income, health insurance, and number of underlying diseases.

^bAdjusted for type of materials, occupation, income, and health insurance. ^cAdjusted for type of materials, gender, and educational level. p < 0.05 with Bonferroni correction (p < 0.0006) was considered statistically significant.

Abbreviation: PIL, Patient information leaflet.

medicine information from PILs.^{3,37} A qualitative study also revealed that PILs were organized and written in short, clear, and easy to understand, that had influenced patients' interest to read the information.⁶

Several studies have demonstrated that grouping information and language used in WMI is important in ensuring understanding.³⁸ Simple, short, patient-centered information can result in better recall and understanding of information compared to standard information.^{7,39} Given the higher ratings for comprehensibility of the PILs, the lack of significant differences in knowledge between the two groups appears surprising. This differs from our previous study in which respondents receiving PILs also rated comprehensibility higher than for PIs, but in addition, had greater safety knowledge.²¹ One possible explanation could be the pre-existing knowledge of the participants in our study, which was not assessed.

The CIRF again proved suitable for evaluating the quality of WMI in a Thai population and was able to detect differences in views among those receiving different forms of WMI. Prior studies in Australia and Belgium have assessed only patient-centered leaflets.^{17,19} Previous studies in Thailand have shown that the CIRF is easy to read and well-organized²⁰ and demonstrated differences in ratings for PILs and PIs for chronic medicines.²¹ This study now demonstrates the application of the CIRF in evaluating the quality of a PI and a PIL for a medicine which can be used short term. Given the widespread practice of distributing PIs to patients in many other countries,² further studies which evaluate the quality of WMI from a patient perspective are needed. Indeed, patients should be involved in evaluating WMI before a product is launched, as occurs in many countries.^{40,41} The CIRF is a valuable addition to user testing as a mechanism for such evaluation.

This study has shown that PILs offer advantages over PIs, in line with other studies in Thailand^{3,21} and elsewhere.^{7,42,43} There is clearly a need for easier, wider access to patient-centred WMI. Manufacturers should be encouraged to produce and test such materials, but health professionals could also assist by advocating and making greater use of the FDA-produced PILs for frequently used medicines.

Strengths and Limitations of the Study

This study used the CIRF, which was previously evaluated for validity and reliability in a Thai population. It compared leaflets which were produced by a manufacturer and the Thai FDA, not leaflets specifically designed for the study. However, it is a cross-sectional study, and we did not determine the extent of previous exposure to omeprazole or specific information received about this medicine. Therefore, the minor differences found in knowledge and perceived benefits and risks between the two forms of WMI could be related to these factors. In addition, the study was conducted in the outpatient setting of only one university hospital and most participants had a high level of education. Also, despite random allocation, participants in the PIL group were older and took more medications than those in the PI group.

Conclusion

Written medicine information for omeprazole is a useful source of the medication use for patients and customers. Using the CIRF showed that PIL provided better comprehensibility, usability, design quality and satisfaction compared to the PI for the same medicine. However, the PI was associated with higher perceived risks, but overall safety knowledge was similar in both groups. The CIRF could be practically used for evaluation of PI and PIL before distributing to the consumers.

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Disclosure

The authors report no conflicts of interest in this work.

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