

# Creating and Appraising a Patient Educational Pamphlet for Migraine Sufferers

Nithya Raju\*, Divya Palaniappan, Femina Hakkim, Gayathri Palani, Jensilin Devakumari Thilagar, Jessly Lalu

Department of Pharmacy Practice, Swamy Vivekanandha College of Pharmacy, Elayampalayam, Tiruchengode, Namakkal, Tamil Nadu, INDIA.

## ABSTRACT

**Background:** Migraine, an intricate genetic ailment, is identified by recurrent, intense headaches that typically impact one side of the head and frequently come with symptoms such as nausea and heightened sensitivity to light. Patient Education (PE) holds a crucial position in the management of migraines, serving as a fundamental element for both prevention and treatment. The objective of this study was to develop Patient Information Leaflets (PILs), assess their reception, and appraise their accessibility to individuals experiencing migraines. **Materials and Methods:** In this study, a patient information pamphlet was created and disseminated to 72 patients with incidence of migraine at a tertiary care hospital in Tamil Nadu. The patients' understanding of the illness was evaluated using both the Flesch and Flesch-Kincaid Readability Test and the User Testing Readability Test. **Results:** We developed a Patient Information Leaflet (PIL) tailored for individuals suffering from Migraine. Subsequently, we evaluated its readability and user-friendliness. To measure readability, we employed the Flesch Reading Ease (FRE) score, where a score below 60 suggests difficulty for the general population. Our PIL attained an average FRE score of 73.9, classifying it as "relatively straightforward" to read. **Conclusion:** The research findings demonstrated that patients with migraine positively received the Patient Information Leaflets (PILs). Moreover, the study revealed a noteworthy enhancement in patient knowledge following their engagement with these PILs.

**Keywords:** Migraine, Patient Information Leaflet, Readability, Usability, Accessibility, Prevention.

## Correspondence:

**Mrs. Nithya Raju**

Department of Pharmacy Practice,  
Swamy Vivekanandha College  
of Pharmacy, Elayampalayam,  
Tiruchengode-637205, Namakkal,  
Tamil Nadu, INDIA.

Email: nityapharma14@gmail.com

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## INTRODUCTION

Migraine, a complex genetic condition, is characterized by recurring, severe headaches that usually affect one side of the head and are often accompanied by symptoms like nausea and increased sensitivity to light. The term "Migraine" has its origins in the Greek word "Hemikrania," which evolved into the Latin term "Hemigranea" and eventually became "migraine" in French. Migraine attacks are intricate neurological processes that can last from hours to days.<sup>1</sup> Common issues associated with these episodes include dizziness, ear pain, fullness in the head or ears, sinus pressure, and sometimes hearing loss. Fortunately, these atypical migraine symptoms can usually be effectively treated using established protocols designed for classic migraine headaches.<sup>2</sup> Migraine, one of the most prevalent neurological disorders, has significant social and economic impacts. It encompasses various symptoms, such as headache, nausea, sensitivity to sensory stimuli, and, in 20% of cases, temporary visual disturbances or neurological symptoms known as aura.<sup>3</sup>

Migraine, with a prevalence rate of 11.7%, represents a significant public health concern with implications for impairment and increased healthcare costs, adversely affecting one's quality of life.<sup>4</sup> Patients should be aware of the differences between various treatment approaches and medications. Approximately 90% or more of migraine patients have used acute treatments at some point, but there are multiple non-pharmacological methods employed as well.<sup>5</sup> The International Headache Society has categorized migraines into subtypes:

### Migraine without Aura

These recurrent headache episodes endure for duration of 4 to 72 hr, typically impacting one side of the head. These conditions are defined by a pulsating discomfort ranging from moderate to severe, which worsens with physical activity, and often accompanied by feelings of nausea, as well as heightened sensitivity to light and sound.

### Migraine with Aura

These repetitive, reversible episodes typically manifest as one or more unilateral symptoms affecting vision, hearing, speech, motor function, brainstem, or retina. These symptoms are followed by the onset of a headache and other accompanying



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migraine symptoms. The aura phase of this condition is of short duration, lasting only minutes.

### Chronic Migraine

This type involves headache-like symptoms occurring at least eight days a month, with at least 15 of those days affected, persisting for at least three months.<sup>1</sup>

The causes of migraine are linked to various neurotransmitter systems such as GABA-ergic, glutamatergic, dopaminergic, and serotonergic pathways. Genetics plays a substantial role, accounting for approximately 50% of the disease's heritability, with numerous documented genetic variants affecting the expression of proteins, enzymes, receptors, and channels within these systems. Although linkage studies have limits in identifying genetic connections for complex variables like migraines, genome-wide association studies, or GWAS, were recently carried out on recurrent migraines.<sup>6</sup> Migraine prevalence varies with age and gender. Boys tend to experience migraines earlier than girls. Women are two to three times more likely than men to suffer from migraines, with both sexes experiencing the highest incidence around midlife. Some individuals experience frequent or prolonged migraine attacks, causing significant discomfort and impairment.<sup>7</sup> Patient Education (PE) plays a pivotal role in managing migraines, both for prevention and treatment. It is a cornerstone of migraine care, with the healthcare team aiming to boost patient confidence, increase awareness, and provide essential support for effective self-management.<sup>8-10</sup>

### Epidemiology

Migraine stands as one of the most common neurological disorders on a global scale, affecting an estimated 1.1 billion people each year. Its prevalence varies significantly among nations, with rates ranging from 8,277 to 22,400 cases per 100,000 individuals.<sup>11</sup> Notably, Belgium and Italy exhibit the highest standardized prevalence rates, whereas Ethiopia and Djibouti have the lowest. Furthermore, it's noteworthy that the age group with the highest incidence and number of new migraine cases encompasses individuals between 10 and 14 years, affecting both genders equally.<sup>12</sup> The aim of this research was to create Patient Information Leaflets (PILs), assess their reception, and evaluate their availability to individuals with migraines.

## MATERIALS AND METHODS

### Preparation of patient information leaflet

A panel of experts, including a doctor, a surgeon, and three professional pharmacists, reviewed and endorsed the Patient Information Leaflet's content, design, and visual symbols. Modifications to the PIL were made in accordance with the expertise committee's suggestions regarding validation of the content.

### Inclusion and Exclusion criteria

Individuals diagnosed with migraine headaches; people greater than 18-years-old and a diverse range of migraine sufferers in terms of age, gender, and migraine severity were included in the study. Studies that include participants with co morbid conditions that may significantly impact migraine management (e.g., other chronic pain conditions) and children were excluded from the study.

### Flesch/Flesch-Kincaid readability test

In this study, a calculation was employed to consider both sentence length and the frequency of multisyllabic words within the text is represented in Table 1. This calculation was utilized to gauge the required reading proficiency level for understanding the Patient Information Leaflet (PIL). The readability of the leaflet was assessed using adult literacy assessment tools referred to as the "FRE" and the "FK-GL." The FRE score assigns a numerical rating ranging from 0 to 100, where a higher grade suggests that the material is easier to learn and acknowledge.<sup>13</sup>

The Patient Information Leaflet has additionally evaluated using the SMOG grade, a measure that indicates the educational level needed to understand the content.<sup>14</sup>

### User testing readability test


The study employed various methods to assess the Patient Information Leaflet developed for migraine patients. One of these techniques involved using readability formulas depending on the number of multisyllabic terms and text length. To assess the readability level of the Patient Information Leaflet, two distinct formulas, namely the "FRE" and "FK-GL," were employed. The FRE score assigns a numerical rating ranging from 0 to 100, with

**Table 1: PIL Readability Tests Score.**

| Comprehensibility Formula   | Level |
|-----------------------------|-------|
| Flesch-Kincaid grade level  | 6.3   |
| Gunning-fog score           | 8.2   |
| Coleman-Liau index          | 10.3  |
| SMOG Index                  | 6.1   |
| Automated readability index | 5.7   |
| Average grade level         | 7.3   |

## MIGRAINE

- A migraine is a moderate or severe headache often felt as a throbbing pain on one side of the head.
- It is a common condition affecting around 1 in 7 people and it often runs in families.




### TYPES

**MIGRAINE WITHOUT AURA**  
(Headache attack lasting 4 - 72 hours)

- Headache that comes in stages
- May experience fatigue, nausea, irritability and sensitivity to light
- Typically on a localized spot on one side of the head


**MIGRAINE WITH AURA**  
(Headache attack lasting 5 - 60 minutes)

- Usually causes visual disturbance for about 30 minutes prior to initial migraine symptoms




## Patient Information Leaflet

# Migraine




Developed by  
Department of Pharmacy Practice, SVCP  
&  
Department of Neurology, VMCH


### MIGRAINE TRIGGERS




lack of sleep




Alcohol




Caffeine




Lemon Juice




Stress




Light



Smell




Weather



Chocolate

### DIAGNOSIS

- Brain MRI
- Head CT
- Eye examination
- Lumbar puncture



### SIGNS AND SYMPTOMS

- Nausea and vomiting
- Sound sensitivity
- Poor Concentration
- Feeling cold
- Recurring headache
- Drowsiness
- Sweating
- Light sensitivity
- Dizziness
- Neck and Body pain

### FOODS TO BE "TAKEN"

- Sweet potato
- Carrot
- Pomegranate
- salmon
- Mint Tea
- Ginger

### FOODS TO BE "AVOIDED"

- Cheese
- Meat
- Citrus fruits
- Pickles
- Artificial sweetener
- Peas

### SELF CARE "TIPS"

- Drink more water stay hydrated
- Apply ice cold or hot compress
- Avoid more screen time
- Find a dark, quiet place to sleep
- Acupuncture therapy
- Do practice yoga
- Do massage for face and scalp
- Do breathing exercise daily

Figure 1: Patient information leaflet for Migraine (English).



**ஓற்றைத் தலைவலி**

- உடலையும் உள்ளத்தையும் உருக்குலைக்கும் ஓற்றைத் தலைவலி - மைக்ரோள் தலைவலி (Migraine) என்பது உடல் உணர்வுகளில் ஏற்படும் மாற்றங்கள், தீவிரமான தலைவலி, குமட்டல் போன்ற அறிகுறிகளைக் கொண்ட நரம்பியல் தொடர்பான ஒரு நோய்வாகும்.
- ஓற்றைத் தலைவலி நோயாளிகளில் கிட்டத்தட்ட மூன்றில் ஒரு பங்கினருக்கு இந்த ஓற்றைத் தலைவலி ஏற்பட சில எச்சரிக்கை அறிகுறிகள் தென்பட ஆரம்பிக்கும்.

**வகைகள்**

**எச்சரிக்கை அறிகுறிகள் இல்லாத ஓற்றைத் தலைவலி**  
(தலைவலி தாக்குதல் 4 மூதல் 72 மணி நேரம் வரை நீடிக்கும்)

- பல்வேறு நிலைகளில் காணப்படும்
- சோர்வு, குமட்டல், எரிச்சல் மற்றும் ஒளியை உணர்ந்தல் ஆகிய அறிகுறிகளை உணரலாம்

**பொதுவாக சில நேரங்களில், தலையின் குறிப்பிட்ட பகுதியில் தலைவலியை உணரலாம்**

**எச்சரிக்கை அறிகுறிகள் கொண்ட ஓற்றைத் தலைவலி**  
(தலைவலி தாக்குதல் 5 மூதல் 60 நிமிடங்கள் வரை நீடிக்கும்)

- ஓற்றைத் தலைவலி அறிகுறிகள் வருவதற்கு 30 நிமிடங்களுக்கு முன்பே பார்வையில் சிறிது தொந்தரவு ஏற்படும்

**தூண்டுதல்**

- தூக்கமின்மை
- மது
- காபி
- அழகிசை சாறு
- யான அழுத்தம்
- வெளிச்சம்
- வானவரை
- வானவியல்
- சாக்லேட்

**நோயறிதல்**

- மூளை MRI
- தலை CT
- கண் பரிசோதனை

**நோயாளி தகவல் துண்டுப்பிரசுரம் "ஓற்றைத் தலைவலி"**

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**அறிகுறிகள்**

- குமட்டல் மற்றும் வாந்தி
- ஒளி சகிப்பின்மை
- கவனமின்மை
- உடற் சமநிலை குழம்புதல்
- தொடர்ச்சியான தலைவலி
- மயக்கம்
- வியர்வை
- ஒளி சகிப்பின்மை
- தலைச்சுற்றல்
- கழுத்து மற்றும் உடல் வலி

**எடுக்க வேண்டிய உணவுகள்**

- சக்கரவல்லி கிழங்கு
- கேரட்
- மாதாளைப் பழம்
- காலா மீன்
- புதினா தேநீர்
- இஞ்சி

**தவிர்க்க வேண்டிய உணவுகள்**

- பாலாடைக்கட்டி
- இறைச்சி
- சிட்ரஸ் பழங்கள்
- ஊறுகாய்
- பச்சை பட்டாணி
- செயற்கை இனிப்பு

**சுய் பாதுகாப்பு குறிப்புகள்.**

- அதிக தண்ணீர் குடிக்கவும், நிரேற்றமாக இருங்கள்
- குளிர் அல்லது சூடான ஒத்தடத்தை பயன்படுத்துங்கள்
- தொலைபேசியில் அதிக நேரம் செலவழிப்பதை தவிர்த்துக் கொள்ளவும்
- இருட்டான மற்றும் அமைதியான இடத்தில் தூங்குவது நல்லது
- அக்குபஞ்சர் சிகிச்சை மேற்கொள்ளுவது நல்லது
- யோகாசனம் மேற்கொள்ளுவது நல்லது
- முகம் மற்றும் உச்சந்தலையில் மசாஜ் செய்வது நல்லது
- தினமும் மூச்சுப் பயிற்சி செய்வது நல்லது

Figure 2: Patient information leaflet for Migraine (Tamil).

higher scores signifying greater readability value is represented in Table 3.<sup>15</sup>

User testing was another approach employed in the study. In accordance with the information in the Patient Information Leaflet, an English and a Tamil user-testing survey was created.

This survey included ten closed-ended (Yes/No) questions. Prior to assessing patients' comprehension, the questionnaire underwent face validation. Migraine patients were given the questionnaire to gauge their existing knowledge, followed by providing them with the PIL in their preferred language (English or Tamil) and allowing them 20 min to read it. Afterward, the

user-testing questionnaire was administered again to reevaluate their understanding.

$$\text{Response evaluation} = \frac{\text{Total number of correct responses}}{\text{Total number of actual responses}}$$

Additionally, an English and Tamil questionnaire was used to gather user opinions about the content, structure, and design of the PIL. This survey consisted of four questions, each scored between one and five. The final scores were interpreted as follows:

- "Good" readability fell within the range of 16 to 20.
- "Average" readability was classified between 10 and 15.
- "Poor" readability was indicated by scores less than 10.

These scores indicate the varying readability levels of the Patient Information Leaflet as assessed by different readability formulas.

## Sample Size

The study determined that a minimum sample size of 72 was needed based on changes in patient knowledge scores before and after intervention.

## Socio Demographic Details

Demographically, out of the 72 enrolled patients, 37 were male, and 35 were female. The majority fell within the 18 to 50 years age group. The average age of the patient population was 60.4 years with a standard deviation of 8.2. Most patients had a high school education, followed by those with a primary level of education is represented in Table 2.

## RESULTS

**Table 2: Demographic information for patients with migraine (total sample size, n=72).**

| Demographic details   | No: of patients |
|-----------------------|-----------------|
| Age, mean+/-SD        | 60.4±8.2        |
| Gender                |                 |
| Male                  | 37(51.3)        |
| Female                | 35(48.6)        |
| Educational status    |                 |
| Primary school        | 14(19.4)        |
| Middle school         | 19(26.3)        |
| High school           | 28(38.8)        |
| Intermediate          | 5(6.94)         |
| Graduate              | 4(5.55)         |
| Illiterate            | 2(2.77)         |
| Socio-economic status |                 |
| Upper                 | 10(13.8)        |
| Upper middle          | 16(22.2)        |
| Lower middle          | 20(27.7)        |
| Upper lower           | 13(18.05)       |
| Lower                 | 13(18.05)       |
| Comorbid              |                 |
| Hypertension          | 18(25)          |
| Diabetes              | 22(30.5)        |
| Hypertension+Diabetes | 27(37.5)        |
| Family history        | 5(6.94)         |
| Social history        |                 |
| Smoking+Alcohol       | 30(41.6)        |
| Smoking               | 18(25)          |
| Alcoholic             | 24(33.3)        |
| Diet                  |                 |
| Vegetarian            | 24(33.3)        |
| Mixed                 | 48(66.6)        |

**Table 3: User-Testing Scores of patient information leaflets.**

| Type of PIL users         | Pre-test score | Post-test score | Mean Difference±SD |
|---------------------------|----------------|-----------------|--------------------|
| Tamil(n=35)               | 42.2±12.6      | 64.3±7.6        | 22.1±8.4           |
| English(n=37)             | 46.6±9.4       | 74.3±10.6       | 27.6±11.0          |
| Overall PILs Users (n=72) | 44.2±10.1      | 69.6±8.4        | 24.3±9.2           |

**Table 4: User-opinion scores of patient information leaflets.**

| User Opinion Category | No. of Patients |
|-----------------------|-----------------|
| Tamil:                |                 |
| Good                  | 39(78)          |
| Average               | 11(22)          |
| Poor                  | --              |
| English:              |                 |
| Good                  | 12(54.5)        |
| Average               | 8(36.3)         |
| Poor                  | 2(9.09)         |
| Overall PILs users:   |                 |
| Good                  | 51(70.8)        |
| Average               | 19(26.3)        |
| Poor                  | 2(2.7)          |

**Table 5: Readability and Usability of Patient Information Leaflet.**

| Category    | Tamil (n=35) | English (n=37) |
|-------------|--------------|----------------|
| Readability | 20.7         | 25.8           |
| Usability   | 22.8         | 27.6           |

## DISCUSSION

Migraine headaches exhibit a wide spectrum of intensity, ranging from relatively mild to extremely severe. They are frequently described as a pulsating or throbbing sensation. These headaches are not limited to a specific location on the head, neck, and face; they can occur in various areas, although they tend to affect one side more prominently. In their most severe form, migraine headaches are often characterized by heightened sensitivity to sensory stimuli such as loud sounds, bright lights, and certain odors. Nausea is a common and debilitating symptom associated with migraines. This nausea tends to worsen with physical activity and can significantly hinder a person's ability to carry out their daily activities. In this research, we created a Patient Information Leaflet (PIL) represented in Figures 1 and 2 specifically designed for individuals with Migraine. The Table 1 presents readability scores for a given text using various formulas, revealing that the text generally falls within a 7<sup>th</sup>-8<sup>th</sup>-grade reading level across different assessments. Specifically, the Flesch-Kincaid Grade Level places it at 6.3, the Gunning-Fog Score at 8.2, the Coleman-Liau Index at 10.3, the SMOG Index at 6.1, and the Automated

Readability Index at 5.7. On average, these scores collectively suggest that the text is comprehensible to readers at a 7<sup>th</sup>-8<sup>th</sup>-grade level, indicating its overall readability and complexity. The majority of Tamil-speaking users have a "Good" opinion (78%) of the PILs, while a smaller portion has an "Average" opinion (22%). In contrast, English-speaking users have a more balanced distribution, with 54.5% finding it "Good," 36.3% rating it as "Average," and 9.09% considering it "Poor" value is represented in Table 4. Understanding the preferences and needs of different user groups can help in tailoring PILs for maximum effectiveness. This could involve simplifying language, using visuals, or addressing specific concerns expressed by users. In Tamil, the readability score is 20.7. In English, the readability score is higher at 25.8 is represented in Table 5. In Tamil, the usability score is 22.8. In English, the usability score is higher at 27.6 is represented in Table 5. The data shows that content in English tends to have both higher readability and usability scores compared to content in Tamil. These findings could be influenced by the specific audience or context in which the content is presented. It's important to consider the linguistic and cultural background of the readers when assessing readability and usability. If the goal is to make



content equally accessible in both languages, the data suggests that efforts may need to be made to improve the readability and usability of Tamil content. Higher usability scores may indicate that English content is more user-friendly, possibly due to factors such as formatting, layout, or navigation. Understanding what contributes to this difference can guide improvements. This table compares pre-test and post-test scores for two groups of PIL users, Tamil and English speakers. It shows that both groups improved after using the PILs, with English speakers showing a slightly larger score increase. Overall, all users had a mean score improvement of 24.3. Conducting further surveys and obtaining qualitative feedback from users can provide deeper insights into their opinions. This can inform ongoing improvements to PILs. Combining both languages, the overall perception of PILs is positive, with 70.8% of users rating them as "Good."

However, there is still a significant portion (26.3%) with an "Average" opinion and a smaller but notable portion (2.7%) with a "Poor" opinion. We then assessed its readability and usability. To gauge readability, we used the Flesch Reading Ease (FRE) score, with a score below 60 indicating difficulty for the general public. Our PIL achieved an average readability score of 73.9, categorizing it as "fairly easy" to read. This indicates that patients are likely to find it acceptable and comprehensible. We also used the FK-GL scoring system, which can be translated into Adding 5 to the result gives the reading age. Our PIL's Score for FK-GL was 6.1, roughly equivalent to an 11 to 12-year-old's reading level. In a previous study, a PIL for Diabetic Foot Ulcers (DFU) scored 7.1 on the FK-GL scale.<sup>16</sup>

Furthermore, we made use of the Gunning-Fog index, this evaluates the number of years of formal education required for an initial comprehension of written material. Our PIL received a Gunning-Fog score of 8.5, indicating clear and accessible text. The Coleman-Liau index rated it at 10.5, suggesting suitability for 10<sup>th</sup> to 11<sup>th</sup> graders.<sup>17</sup> The SMOG index was employed to assess the educational level required to comprehend the text. Furthermore, the Automated Readability Index (ARI) measured comprehension, resulting in a score of 5.9, akin. This corresponds to an upper primary school reading level, approximately equivalent to grade 6, suitable for readers aged 11 to 12 years. In our study, we combined user testing with the FRE/FK-GL approach to assess the readability of the Patient Information Leaflet.<sup>14</sup> Compared to previous research that solely used formulaic methods, we combined user testing and user feedback. Impressively, 82.4% of respondents rated the PIL's content, readability, and design favorably.<sup>18</sup> Furthermore, our research unveiled a noteworthy improvement in user testing scores after the intervention, with scores ascending from 44.2 to 69.6 ( $p < 0.05$ ). This finding underscores the effectiveness of Patient Information Leaflets in enhancing patient comprehension and acceptance.<sup>15,19</sup>

## CONCLUSION

The research findings states that patients with migraine positively received the Patient Information Leaflets (PILs). According to user feedback, nearly all of participants scored the PILs' content, readability, and appearance in excellent ratings. This study clearly demonstrates that Patient information leaflets (PILs) help migraine patients understand their condition, make informed treatment decisions, avoid side effects, communicate with healthcare providers, and improve quality of life.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**PIL:** Patient Information Leaflet; **FRE:** Flesch Reading Ease; **GWAS:** Genome-Wide Association Studies; **PE:** Patient Education; **SMOG:** Simple Measure of Gobbledygook; **FK-GL:** Flesch Kincaid Grade Level.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was carried out after taking permission from the Institutional Ethics Committee of Vivekanandha Medical Care Hospital (Ref.: SVCP/IEC/OCT/2023/36).

The consent was taken from the patient to participate in the study.

## SUMMARY

This content discusses migraine, a complex genetic condition characterized by severe recurring headaches, often accompanied by symptoms like nausea and sensitivity to light. The origins of the term "migraine" are traced back to Greek and Latin words. Migraine attacks can last from hours to days and may involve various symptoms, including dizziness and sensory issues. The prevalence of migraines is significant and varies with age and gender, with women being more affected. The content emphasizes the importance of patient education in managing migraines and describes the research objective of creating Patient Information Leaflets (PILs) for migraine patients. It details the methods used to prepare and assess the PILs, including readability tests and user testing. The results show that the PILs were generally well-received by patients, leading to an improvement in their knowledge about migraines. In conclusion, the study suggests that patient education through PILs can play a crucial role in enhancing the understanding of migraine among individuals

suffering from this condition. The content also provides readability and usability scores for the PILs in both English and Tamil, along with demographic information about the patients involved in the study.

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