

Development and validation of patient information leaflet for coronary heart disease patients

B. C. Vinay, C. S. Shastri, Subramanyam Kodangala¹, Uday Venkat Mateti, Krishna Bhat²

Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences, Nitte (Deemed to be University),

¹Department of Cardiology, K.S. Hegde Medical Academy, Justice K.S. Hegde Charitable Hospital, Nitte (Deemed to be University),

²Department of Statistics, K.S. Hegde Medical Academy, Nitte (Deemed to be University), Deralakatte, Mangaluru, Karnataka, India

Abstract

Background: Patient information leaflets (PILs) are effectively used to improve the patient's knowledge about medications, disease, diet, and lifestyle modifications.

Aim: This study aims to develop and evaluate PILs for coronary heart disease patients.

Materials and Methods: Primary, secondary, and tertiary resources were used to develop PILs. The developed PILs were validated by four doctors, four academic pharmacists, and one dietician. PILs design and layout was prepared using barker able leaflet design (BALD) criteria. PILs readability was assessed using the Flesch Reading Ease test (FRE), Flesch–Kincaid Grade Level (FKGL), and user readability methods. User opinion on PILs content and design was obtained from patients.

Results: The FRE and FKGL readability scores were 61.5 and 7.4, respectively. The BALD criteria scores for English, Kannada, and Malayalam PILs were 28, 27, and 26, respectively. The overall user testing readability means scores had significantly improved from 45 to 79.30. Nearly 82.55% of patients rated the PILs as good design and content.

Conclusion: The developed leaflet met the standard criteria for easy reading and comprehension. The majority of the patients gave good opinion on the content and design of the PILs.

Keywords: Coronary heart disease, patient counseling, patient information leaflet, readability

Address for correspondence: Dr. C. S. Shastri, Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences Paneer, Nitte (Deemed to be University), Deralakatte, Mangaluru - 575 018, Karnataka, India.

E-mail: drcshastry@gmail.com

Received: 13-04-19, **Revised:** 11-09-19, **Accepted:** 16-09-19, **Published:** 20-12-19.

INTRODUCTION

Coronary heart disease (CHD) is also termed as coronary artery disease or ischemic heart disease. It is a condition in which heart receives less oxygenated blood due to atheroma, thrombosis, or spasm of coronary arteries.^[1] CHD comprises acute coronary syndromes, unstable angina, and myocardial infarction. These are the frequent causes of death in cardiovascular disease

patients.^[2] Hypertension, smoking, increased serum cholesterol, diabetes mellitus, mental stress, and obesity are considered as potential risk factors for CHD. An individual with all these risk factors will have increased risk of developing CHD.^[1] According to the World Health Organisation and Indian Council of Medical Research, CHD along with diabetes and hypertension are going to be the major causes of morbidity and mortality by 2020.^[3]

Access this article online	
Quick Response Code:	Website: www.picronline.org
	DOI: 10.4103/picr.PICR_58_19

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How to cite this article: Vinay BC, Shastri CS, Kodangala S, Mateti UV, Bhat K. Development and validation of patient information leaflet for coronary heart disease patients. *Perspect Clin Res* 2021;12:83-6.

CHD is best managed when positive health behaviors become part of long-term habits of life. Almost half of the patients with a history of heart disease are poorly aware of CHD symptoms and the impending heart attack. Delay in seeking medical attention is due to the poor knowledge about CHD disease symptoms and its risk factors. Thus, providing information to the patient or the patient's representative regarding their disease, medications, and lifestyle modifications will improve the quality of life (QoL) of the patients. Many studies revealed that education which has provided verbally to the patients usually fails because of confusion and forgetfulness. Therefore, patient information leaflets (PILs) are universally accepted counseling aids to provide information about their lifestyle modifications, disease, and medications.^[4-6]

MATERIALS AND METHODS

Study design

This study was carried as part of the study on the impact of pharmaceutical care on the clinical outcomes and QoL for CHD patients in a tertiary care teaching hospital. Central Ethics Committee clearance (Ref. no. NU/CEC/2018/01) was obtained before initiating the study. Patients aged above 18 years and diagnosed with CHD with or without comorbidities were enrolled in the study. Literate patients were enrolled from both the inpatient and outpatient departments of cardiology. Pretest and posttest design were carried out for assessing the readability of PILs. Demographic details such as comorbidities, age, sex, and educational status were obtained from the patients. Kuppuswamy socioeconomic scale^[7] was used for calculating the enrolled patient's socioeconomic status.

The sample size was calculated based on 80% of power and 5% of level of significance; standard deviation is 12 and the minimum significant difference is 4.^[8] The minimum sample size required for the study is 73, anticipating dropout rate is 15%, and the required sample size is 86. The participants were enrolled proportionally based on the availability in different languages.

Development and validation of patient information leaflets

Initially, PILs are prepared in English by referring primary, secondary, and tertiary resources. Various review and research articles related to CHD were referred as primary resources.^[4] Secondary resources included up-to-date Micromedex, WebMD, and Medscape. The tertiary resources include standard books such as *Clinical Pharmacy and Therapeutics*^[1] and *Pharmacotherapy A Pathophysiological Approach*.^[2] Information on the symptoms, risk factors,

diagnosis, diet, and lifestyle, commonly prescribed medications, and the importance of regular checkups were included in the PILs. The content of PILs was validated by the expert committee consisting of four doctors, four academic pharmacists, and one dietician. For the validation of PILs, checklist criteria were provided to the expert committee. The necessary changes in PILs were made based on the suggestion of the committee before assessing the readability. PILs design and layout was developed using barker able leaflet design (BALD) criteria. The BALD criteria scores were calculated based on the font size, indenting, separation between lines, alignment, box type text, number of colors, use of pictures, and good-quality paper. As per the BALD criteria, a PIL score between 20 and 25 (maximum score is 32) is considered as good layout and design.^[9-11] The prepared and validated PILs in the English version was translated to Kannada and Malayalam languages, using forward and backward translation procedure; then, these leaflets were also assessed for readability.

Assessment of readability

PILs readability was assessed using Flesch–Kincaid Grade Level (FKGL),^[12] Flesch Reading Ease test (FRE),^[13] and user testing questionnaire. User-testing questionnaire was developed based on the content of PILs. It includes 10 validated multiple choice questions. The baseline knowledge of CHD patients (English or Kannada or Malayalam language) was assessed using user-testing questionnaire. After determining the baseline knowledge, the patients were allowed to read the PILs for 20 min. After reading the PILs, posttest was performed using the same user testing questionnaires to reassess the knowledge. The user-testing response evaluation was assessed using the following formula:

$$\text{Response evaluation} = \frac{\text{Total number of correct responses}}{\text{Total number of questions}} \times 100$$

After user testing, user opinion on PILs content, design, and layout were obtained from patients. For this, four user-opinion questions were prepared and validated. The scores for this questionnaire were ranged from five to one.

The interpretation of user opinion scores assessment is as follows:^[8,14]

- If the score is 14–20, the content, design, and layout of the PIL is considered as good
- If the score is 9–14, the content, design, and layout of the PIL is considered as average
- If the score is 0–9, the content, design, and layout of the PIL is considered as poor.

RESULTS

Baker able leaflet design scores

PILs design and layout scores were obtained by BALD criteria. The scores obtained for the English, Kannada, and Malayalam version of PILs were 28, 27, and 26, respectively.

Sociodemographic details of the patients

One hundred and one individuals were included according to the study criteria. Of the 101 patients recruited for this study, 73 (72.77%) were males, 86 (85.14%) were literates, and 51 (50.49%) belong to the upper lower socioeconomic status. Sociodemographic details of the patients are depicted in Table 1.

Readability test score

The FRE readability test scores were found to be 61.5; this indicates that the prepared leaflet is a standard one and it is easier to read and understand. FKGL test score was found to be 7.4; this means the prepared leaflet can be understood between the grade levels 7–8. Readability of Kannada, English, and Malayalam PIL was assessed by user-testing questionnaires. Of the 86 PILs users, Kannada leaflet users were found to be more – 40 (46.511%) followed by English leaflet users – 26 (30.23%), and Malayalam leaflet users – 20 (23.52). User-testing readability mean score for overall leaflet user had significantly improved from 45 to 79.30. Complete user-testing readability scores of Kannada, English, and Malayalam versions of PILs are depicted in Table 2.

User opinion score

Overall, 82.55% of patients rated the PILs as good design and content. The user-opinion scores of English, Kannada, and Malayalam version PILs are presented in Table 3.

DISCUSSION

This study was involved in the development and validation of PILs for CHD, and the previous researches developed and validated leaflets on peptic ulcer, hypertension, diabetes, asthma,^[11] hemodialysis^[14] and chronic obstructive pulmonary disease,^[15] diabetic foot ulcer,^[16] and tuberculosis.^[8] This study is unique, compared to previous studies as many of the earlier studies used either western formula or user-testing questionnaires to assess the readability of PILs. In the present study, readability was evaluated by both western formula and user testing questionnaires.^[4,11,14,15] The mean BALD score for developed PILs in English language was better compared to previous studies,^[11,15,16] and the score was similar to Mateti *et al.*^[14] The mean BALD score for the prepared PILs in the Kannada language was 27 whereas 26 in previous studies.^[10,16]

Table 1: Demographic details of coronary heart disease patients recruited for the study

Demographic details	Number of patients (%)
Age, mean±SD	58.06±8.35
Gender	
Male	73 (72.27)
Female	28 (27.73)
Educational status	
Primary school	23 (22.77)
Middle school	17 (16.83)
High school	23 (22.77)
Intermediate	4 (3.96)
Graduate	19 (18.82)
Illiterate	15 (14.85)
Socioeconomic status	
Upper	2 (1.98)
Upper middle	9 (8.91)
Lower middle	35 (34.66)
Upper lower	51 (50.49)
Lower	4 (3.96)
Comorbid	
Hypertension	22 (21.78)
Diabetes	27 (26.73)
Hypertension + diabetes	18 (17.82)
Family history	16 (15.84)
Social history	
Smoking + alcoholic	24 (23.76)
Smoking	13 (12.87)
Alcoholic	12 (11.88)
Diet	
Vegetarian	22 (21.78)
Mixed	79 (78.22)

SD=Standard deviation

Table 2: User-testing readability scores of patient information leaflets

Type of users	Mean±SD		P
	Pretest scores	Posttest scores	
Kannada (n=40)	39.75±10.73	78.25±9.57	<0.00001
English (n=26)	51.53±12.86	81.15±9.51	Result is significant <0.00001
Malayalam (n=20)	47±10.80	79±8.52	Result is significant <0.00001
Overall PILs users (n=86)	45±12.43	79.30±9.30	Result is significant <0.00001

SD=Standard deviation, PILs=Patient information leaflets

Table 3: User-opinion scores of patient information leaflets

Type of users	Number of patients (n=86), n (%)
Kannada	
Good	35 (87.5)
Average	5 (12.5)
Poor	-
English	
Good	21 (80.77)
Average	5 (9.23)
Poor	-
Malayalam	
Good	15 (75)
Average	5 (25)
Poor	-
Overall PILs users	
Good	71 (82.55)
Average	15 (17.45)
Poor	-

PILs=Patient information leaflets

In our study, the readability score was attained 7.4 for FK-GL and 61.5 for the FRE. In another study, FRE score was 73.9 better than our study, and the FK-GL score was 6.1 lesser than our study.^[16] The previous studies achieved 68.3 scores for FRE which is more compared to our study and 7.4 for FK-GL which is similar to our study.^[15] FRE score was 72.4 and 80 in other studies which was more compared to our study.^[4,11] Most of the studies used western scales to assess readability, and these scales are not suitable for Indian languages. Hence, the present study was attempted to evaluate the readability of Kannada and Malayalam language leaflet by user testing. In our research, the mean score of user-testing questionnaires had notably improved from 45 to 79.30 which is better than the previous researches. The improvement in the scores was due to the provision of PILs (information about symptoms, risk factors, diagnosis, diet, and lifestyle, commonly prescribed medications, and the importance of regular checkups) and allowed the participants to read the PILs for 20 min. After reading the PILs, the posttest was done to reevaluate the knowledge. In the previous study, the overall user-testing mean score was 44.25–69.62^[14], whereas the overall user-testing mean score for another study was 43.4–69.7.^[16] In previous research work, the overall user opinion on the leaflet content and design was 81.44%^[14] and 82.4% in another research study^[16], which is almost similar to our study. The limitations of the study include the following: long-term retention of knowledge was not evaluated and the readability of Kannada and Malayalam language PILs was not performed due to the unavailability of the readability formulae in the Indian languages.

CONCLUSION

The readability of the Indian language PILs was assessed in a better way by user-testing questionnaires compared to the western scales of FRE and FK-GL readability methods. In our study, the knowledge about the disease and medication had significantly been improved after reading the PILs. Nearly 82.55% of patients rated the PILs as good design and content.

Acknowledgment

Researchers would like to thank all the faculties of Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences and Department of Cardiology, K.S. Hegde Medical Academy, Justice K.S. Hegde Charitable Hospital, for their valuable suggestions advice. Researchers also would like to express their sincere gratitude to

Nitte (Deemed to be University), Mangaluru, for providing the required facilities to carry out our research work.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

- McRobbie D. Coronary heart disease. In: Walker R, Whittlesea C, editors. *Clinical Pharmacy and Therapeutics*. 5th ed. London: Elsevier Ltd.; 2012. p. 312-3.
- Spinler SA, Denus SD. Acute coronary syndromes. In: Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, editors. *Pharmacotherapy A Pathophysiological Approach*. 9th ed. New York: McGraw Hills Education; 2005. p. 291.
- Medindia. Heart Attack; 2016. Available from: <http://www.medindia.net/patients/patientsinfo/HeartAttack.htm>. [Last accessed on 2018 Dec 22].
- Priya JK, Balambigai MS, Sariga N, Sathya M, Andhuvan G. Development and validation of patient information leaflet for heart attack patients. *Int J Pharm Pharm Sci* 2016;8:381-3.
- Mateti UV, Kodangala S, Ummer J. Impact of clinical pharmacist counseling and education on quality of life in patients with acute coronary syndrome. *Indian J Pharm Educ Res* 2016;50:360-7.
- Parthasarathi G, Hansen KN, Nahata MC, editors. *A Text Book of Clinical Pharmacy Practice*. 2nd ed. Universities Press (India) Private Limited, Hyderabad; 2012. p. 60-7.
- Saleem SM. Modified Kuppaswamy scale updated for year 2018. *Paripex Indian J Res* 2018;7:435-6.
- Shrestha A, Rajesh V, Dessai SS, Stanly SM, Mateti UV. Preparation, validation and user-testing of pictogram-based patient information leaflets for tuberculosis. *Pulm Pharmacol Ther* 2018;51:26-31.
- Baker S. Who can read consumer product information? *Aust J Hosp Pharm* 1997;27:126-31.
- Vooradi S, Acharya LD, Seshadri S, Thunga G, Vijayanarayana K. Preparation, validation and user-testing of patient information leaflets on diabetes and hypertension. *Indian J Pharm Sci* 2018;80:118-25.
- Adepu R, Swamy MK. Development and evaluation of Patient Information Leaflets (PIL) usefulness. *Indian J Pharm Sci* 2012;74:174-8.
- Flesch R, Kincaid JP. Flesch – Kincaid Grade Level Readability Test; 2014. Available from: <http://www.readabilityformulas.com/flesch-grade-levelreadability-formula.php>. [Last accessed on 2018 Dec 22].
- Flesh R. Flesh Readability Index; 2014. Available from: <http://www.readabilityformulas.com/flesh-reading-ease-readability-formula.php>. [Last accessed on 2018 Oct 22].
- Mateti UV, Nagappa AN, Attur RP, Bairy M, Nagaraju SP, Mallayasamy S, *et al.* Preparation, validation and user-testing of pictogram-based patient information leaflets for hemodialysis patients. *Saudi Pharm J* 2015;23:621-5.
- Suhaj A, Mohan MK, Mohan MK, Mohapatra AK, Magazine R, Mallikarjuna RC, *et al.* Development and readability assessment of patient information leaflet for chronic obstructive pulmonary disease. *Asian J Pharm Health Sci* 2015;5:1237-41.
- Sekhar MS, Mk U, Vyas N, Rodrigues GS. Development and evaluation of patient information leaflet for diabetic foot ulcer patients. *Int J Endocrinol Metab* 2017;15:e55454.