

Development and Validation of a Breast Cancer Information Leaflet to Advance Health Literacy in Oncology: A Methodological Study

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ABSTRACT

Introduction: Breast cancer continues to be a significant global health concern, with increasing incidence rates, particularly in Asian populations. Providing patients with clear and reliable educational resources is essential for improving awareness and involvement in their care.

Aim: To develop and validate a Patient Information Leaflet (PIL) for individuals with breast cancer to enhance their understanding of the disease, its treatment, and proper medication use.

Materials and Methods: This methodological validation study was conducted at Department of Pharmacy Practice, KLE College of Pharmacy, KAHER, Belagavi Karnataka, India, and KLE Cancer hospital, Belagavi, over a period of four months from July 2025 to November 2025. The study followed a structured multi-phase process for the development and validation of the PIL, which was prepared using current oncology guidelines. A 10-item evaluation questionnaire was developed and reviewed by a multidisciplinary panel of experts, who rated each item on a 5-point Likert scale. Content validity was assessed using Item-level and Scale-level Content Validity Indices (I-CVI and

S-CVI). The responses were analysed using Statistical Package for Social Sciences (IBM SPSS) version 20.0, with Cronbach's alpha applied to assess internal consistency and readability indices used to evaluate the suitability of the leaflet for the target population.

Results: A total of 60 experts participated in the validation. The PIL showed good internal consistency (Cronbach's $\alpha=0.870$). Content validity indicated strong expert agreement, with I-CVI values ranging from 0.81 to 0.96 and an S-CVI/Ave=0.91. Readability assessment yielded a Grade A rating (Flesch Reading Ease: 65.21; Flesch-Kincaid Grade Level: 5.53), indicating that the leaflet is clear, easy to understand, and appropriate for a broad audience.

Conclusion: The validated leaflet serves as an effective and accessible educational tool for enhancing breast cancer awareness and supporting informed decision-making. Its high reliability and excellent readability make it suitable for clinical use as well as community health education. Further patient-centered evaluations are recommended to assess its impact on real-world understanding and health outcomes.

Keywords: Breast neoplasms, Education materials, Patient education, Readability

INTRODUCTION

Across the world, breast cancer continues to top the list of the most frequently detected cancers [1]. Breast cancer continues to be a critical global health issue, with about 2.3 million new cases recorded in 2022. Around 43% of these cases were reported in Asia, where the disease demonstrates unique trends, differing peak ages, and incidence rates compared to Western regions. The consistent rise in breast cancer cases across many Asian countries highlights the urgent need for region-specific strategies focused on prevention, early detection, and effective treatment [2]. In addition, healthcare professionals need to play an active role in educating patients and the general population about breast cancer. This includes raising awareness of its causes and risk factors, recognising early warning signs, understanding the importance of timely medical evaluation, and promoting knowledge of available treatment options. Such efforts are crucial to improving outcomes and reducing the overall burden of the disease. However, current approaches to patient education are often ineffective. Patients may struggle to fully understand or remember information provided during consultations, especially when complex medical terms are used or when they are under emotional stress [3].

The global rise in breast cancer cases, especially in Asian regions, emphasises the necessity for dependable and easy-to-understand educational materials for patients. Patient Information Leaflets (PILs)

are widely recognised as effective tools for educating patients about their illnesses, prescribed treatments, and necessary lifestyle changes [4]. Research indicates that relying solely on verbal instructions often leads to poor patient understanding and recall. Consequently, written materials such as PILs are commonly used to ensure patients receive clear and accessible information [5]. Written educational resources such as PILs serve as an important supplement to verbal communication by helping patients revisit information, improve understanding, and participate more actively in their care [6]. The development and validation of a PIL for breast cancer patients is essential for providing clear and reliable information about the disease, treatment options, medication use, and possible adverse effects. A well-designed PIL can improve patients' understanding of their condition, encourage active involvement in their care, and promote better adherence to treatment. In addition, accessible written information may help reduce patient anxiety and strengthen health literacy. Despite their usefulness, many available PILs are not consistently structured, may not match the literacy levels of the target audience, and are often developed without systematic evaluation, which can affect their clarity and effectiveness. Ensuring the leaflet's accuracy, readability, and cultural suitability through validation is therefore important for effective patient education. Therefore, evaluating both the content and readability of educational materials is essential. Validation ensures that the information is accurate and relevant,

while readability assessment helps confirm that the material can be easily understood by individuals with varying levels of health literacy [7]. The primary objective of the current study was to design and validate a PIL for breast cancer patients. The leaflet was further assessed for content validity, internal consistency, readability, and information accuracy to ensure it effectively promotes health literacy and patient comprehension.

MATERIALS AND METHODS

This methodological validation study was conducted at Department of Pharmacy, KLE College of Pharmacy, KAHER, Karnataka, India, and associated Oncology Care Settings, over a period of four months, from July 2025 to November 2025, following approval from the Institutional Ethics Committee (IEC No.: KAHER/EC/24-25/D-739).

Inclusion criteria: Eligible participants included healthcare professionals with a minimum of five years of experience in relevant fields such as oncology, general medicine, pharmacy practice, clinical pharmacy, pharmacology, and related health sciences, holding at least a graduate or postgraduate qualification (MBBS, MD, PharmD, M. Pharm, or equivalent) and willing to participate in the evaluation.

Exclusion criteria: Individuals with less than five years of experience, those from unrelated disciplines, or those who did not complete the assessment were excluded.

Sample size: Participants were recruited using purposive sampling. A formal sample size calculation was not performed; instead, all eligible experts available during the study period were included to obtain comprehensive validation. The collected responses were analysed to assess reliability and validity. Internal consistency was evaluated using Cronbach's alpha, while content validity was determined using the Content Validity Index (CVI), including Item-level CVI (I-CVI) and Scale-level CVI (S-CVI), to ensure the relevance and adequacy of the leaflet content.

Study Procedure

Each participant was provided with the leaflet along with a structured questionnaire for evaluation. The development and validation process was carried out in five structured phases to ensure the accuracy, clarity, and reliability of the leaflet content.

Phase I: Development of the PIL

The PIL was developed using evidence-based clinical resources, up-to-date oncology guidelines, and standard patient education materials. It addressed key aspects of breast cancer, including risk factors, clinical features, diagnostic methods, treatment options, medication use, potential adverse effects, self-care practices, and preventive strategies. The content was written in clear and simple language to ensure comprehensibility for individuals with varying levels of health literacy. Visual aids and illustrations were incorporated to enhance understanding and reader engagement.

To further ensure that the leaflet was appropriate for the target population, its readability was evaluated using the Readable® readability assessment platform, which generated Flesch Reading Ease, Flesch-Kincaid Grade level. These measures provided an objective estimate of how easily the information could be read and the level of education required to understand it, thereby helping to ensure that the material is both accessible and effective.

Phase II: Development of the evaluation questionnaire

A structured questionnaire was designed to evaluate the quality and effectiveness of the PIL, comprising 10 items organised into four domains: content clarity and completeness, relevance and practical usefulness, language and presentation, and psychological impact, along with overall quality. Each item was rated using a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). Scores were calculated at both domain and overall levels, where higher

scores indicate better quality and greater acceptability of the leaflet. The tool was developed with guidance from a multidisciplinary panel, including oncologists, pharmacists, academicians, and other healthcare professionals, to ensure its suitability and relevance. The complete questionnaire, along with domain classification and scoring details, is provided separately.

Phase III: Administration of the validation tool

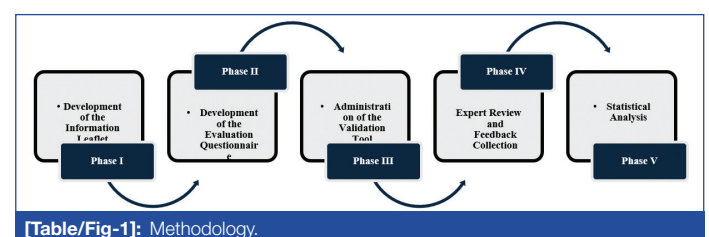
The validation questionnaire was distributed to the selected experts along with the PIL. The validators rated each item using a five-point Likert scale ranging from "strongly disagree" to "strongly agree." This process enabled the systematic collection of quantitative ratings and qualitative feedback on the clarity, usefulness, and applicability of the leaflet.

Phase IV: Expert review and feedback collection

The Patient Information Leaflet (PIL) and validation questionnaire were shared electronically via Google Forms to facilitate convenient participation and efficient data collection. The expert panel comprised oncologists, general practitioners involved in cancer care, oncology pharmacists, hospital pharmacists, clinical pharmacologists, and academic professionals from health science disciplines. All validators had a minimum of five years of professional experience, ensuring an informed evaluation of the leaflet. Based on their recommendations, several revisions were made to enhance its quality, including simplifying complex medical terminology, refining visual illustrations for greater clarity, and adding a section addressing the psychological and emotional impact of breast cancer.

STATISTICAL ANALYSIS

Phase V: Data were coded and analysed using IBM SPSS, version 20.0. Expert responses were summarised using descriptive statistics and reported as mean values and percentages. The reliability of the questionnaire was assessed using Cronbach's alpha, with a value of 0.70 or higher considered acceptable. Content validity was established using the Content Validity Index (CVI), wherein for content-validity analysis, responses rated 4 (Agree) or 5 (Strongly Agree) on the 5-point Likert scale were considered relevant and dichotomised to calculate the Item-level Content Validity Index (I-CVI) and the Scale-level CVI (S-CVI) was calculated as the average of all I-CVI values. Readability indices were also applied to ensure that the leaflet was appropriate for the intended audience [Table/Fig-1].



RESULTS

Demographics

The demographic characteristics of the 60 experts who participated in validating the breast cancer information leaflet are summarised as follows. The panel comprised 32 males (53.33%) and 28 females (46.67%), providing a balanced representation that supported diverse professional viewpoints during the evaluation.

The validators were distributed across three age groups, ensuring perspectives from different stages of professional development. The largest proportion belonged to the 36-45 year age group, typically representing mid-career professionals actively engaged in clinical decision-making and academic responsibilities, 24 (40%). This was followed by participants aged 25-35 years, 20 (33.33%), who contributed contemporary clinical exposure and current

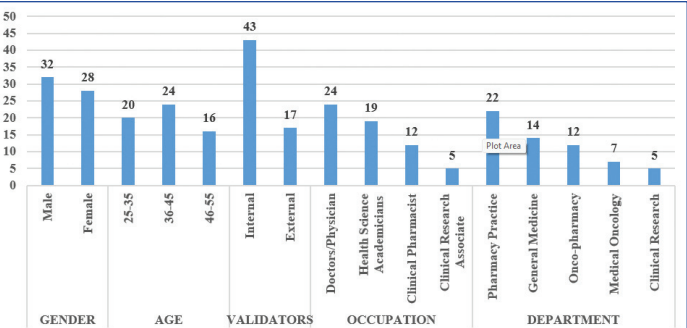
communication practices. Additionally, 16 (26.67%) were aged 46–55 years, contributing substantial experience and long-term clinical insights. The majority of validators were internal experts associated with the Institution, 43 (71.67%), ensuring familiarity with Institutional standards and patient care practices. The remaining 17 (28.33%) were external validators, who provided independent viewpoints, thereby enhancing the neutrality and credibility of the review process.

A range of professional backgrounds was represented. Physicians formed the largest occupational group 24 (40%), providing essential clinical judgment for assessing the accuracy and relevance of the leaflet. Health science academicians accounted for 19 (31.67%), adding educational and research-oriented perspectives. Clinical pharmacists 12 (20%) contributed in medication-related information, particularly relevant in oncology. Clinical research associates, 5 (8.33%), further strengthened the scientific rigour of the validation.

Participants were drawn from several departments, including pharmacy practice 22 (36.67%), general medicine 14 (23.33%), onco-pharmacy 12 (20%), medical oncology 7 (11.67%), and clinical research 5 (8.33%). This multidisciplinary representation ensured that the leaflet was evaluated from multiple professional perspectives, thereby, enhancing its overall reliability and applicability [Table/Fig-2,3].

S. No.	Category	Sub-category	n (%)
1.	Gender	Male	32 (53.33)
2.		Female	28 (46.67)
3.	Age (in years)	25-35	20 (33.33)
4.		36-45	24 (40)
5.		46-55	16 (26.67)
6.	Validators	Internal	43 (71.67)
7.		External	17 (28.33)
8.	Occupation	Doctors/Physician	24 (40)
9.		Health Science Academicians	19 (31.67)
10.		Clinical Pharmacist	12 (20)
11.	Department	Clinical Research Associate	05 (8.33)
12.		Pharmacy Practice	22 (36.67)
13.		General Medicine	14 (23.33)
14.		Onco-pharmacy	12 (20)
15.		Medical Oncology	07 (11.67)
16.		Clinical Research	05 (8.33)

[Table/Fig-2]: Demographic details (N=60).



[Table/Fig-3]: Demographic details presented in a bar chart (N=60).

Cronbach's alpha	No. of items
0.870	10

[Table/Fig-4]: Reliability statistics.

Questions	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	S-CVI
Mean	0.96	0.91	0.91	0.95	0.90	0.88	0.90	0.91	0.81	0.93	0.91

[Table/Fig-5]: Content Validity Index (CVI).

Reliability Statistics

The reliability of the questionnaire used to assess the PIL was examined by calculating Cronbach's alpha to determine the internal consistency of the items included in the instrument. A total of 60 healthcare professionals participated in the validation process, including physicians, pharmacists and health science academicians. Their participation ensured that the evaluation incorporated perspectives from various healthcare disciplines. Each participant responded to the questionnaire using a five-point Likert scale ranging from strongly disagree (1) to strongly agree (5), which allowed a structured assessment of the leaflet.

The analysis produced a Cronbach's alpha value of 0.870, demonstrating good internal consistency among the ten items included in the questionnaire. This finding indicates that the items are closely related and consistently represent the same underlying aspect being assessed by the evaluation tool. In reliability studies, a Cronbach's alpha value above 0.8 is generally interpreted as evidence of strong internal consistency, suggesting that the items in the instrument function together in a coherent manner.

The results show that the questionnaire used to evaluate the PIL provides consistent responses among the evaluators. This supports the appropriateness of the instrument for assessing the clarity, organisation, and presentation of information within the leaflet and for evaluating educational materials developed for patient awareness [Table/Fig-4].

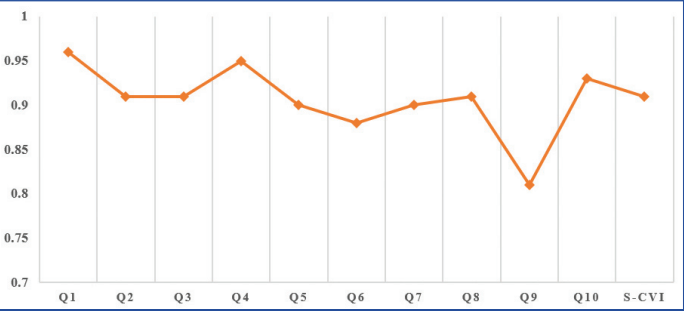
Content Validity Index (CVI)

The content validity of the breast cancer information leaflet was examined using the Content Validity Index (CVI) to ensure that the information presented was appropriate, clear, and relevant to the intended purpose. The Item-Level CVI (I-CVI) scores for all ten items ranged from 0.81 to 0.96, indicating that each component of the leaflet was rated positively by the expert panel and met the recommended standard for acceptability. None of the items fell below the acceptable limit, suggesting that all sections of the leaflet were considered suitable without the need for revision. In addition, the overall Scale-Level CVI (S-CVI/Ave), calculated as the mean of the individual item scores, was found to be 0.91. This value exceeds the commonly accepted benchmark of 0.90, reflecting a high degree of agreement among experts regarding the overall quality and adequacy of the content.

Taken together, these findings indicate that the leaflet provides comprehensive and relevant information about breast cancer clearly and understandably. The consistently strong ratings across all items suggest that the material is well-developed and appropriate for use among the target population. As no major concerns were identified during the evaluation, the leaflet can be considered a reliable educational resource without requiring further modification [Table/Fig-5,6].

Readability Assessment of the PIL

The readability of the PIL was examined using several established readability indices. The analysis showed an overall Grade A rating, suggesting that the leaflet is written in a manner suitable for the general public. The Flesch Reading Ease score of 65.21 indicates that the material falls within the "fairly easy" category, reflecting the use of clear vocabulary and uncomplicated sentence structures. In a similar way, the Flesch-Kincaid Grade Level (5.53) and Gunning Fog Index (6.03) suggest that the content can be understood by readers with late primary or early secondary school education. The Coleman-Liau Index (8.8) and the SMOG Index (7.96) also



[Table/Fig-6]: Content Validity Index (CVI).

indicate that the leaflet corresponds to the comprehension level of middle-school readers, making the information accessible to a wide audience.

Additional readability indicators further reinforce these results. The Automated Readability Index (5.33) and the Dale–Chall readability score (5.47) suggest that the leaflet can be easily understood by individuals with average reading skills. Similarly, the LIX score (33.04) and the RIX value (5) indicate relatively simple sentence patterns and moderate textual complexity. The Powers–Sumner–Kearl grade level of 4.49 shows that the material can be comfortably read at an elementary education level, highlighting the accessibility of the leaflet for patients. Taken together, these measures demonstrate that the content is written in clear and uncomplicated language appropriate for patient education. In addition, the leaflet includes 74 paragraphs and 95 sentences, which are structured in a well-organised manner. This balanced distribution of paragraphs and sentences helps maintain clarity and supports easier comprehension for readers [Table/Fig-7].

Parameters	Score/Level	Rating	Interpretation
Overall rating	—	A	High readability and appropriate for general public
Flesch reading ease	65.21	A	Fairly easy to read; plain English style
Flesch–Kincaid grade level	5.53	A	Suitable for 5 th –6 th grade readers
Gunning fog index	6.03	A	Easily understood by early teens
Coleman–Liau index	8.8	A	Appropriate for secondary school level
SMOG index	7.96	A	Readable by 7 th –8 th grade level
Automated Readability Index (ARI)	5.33	A	Comprehensible by average readers
Dale–Chall readability score	5.47	A	Easily understood by most adults
LIX score	33.04	A	Simple, easy-to-read text
RIX score	5	A	Moderate text complexity
Powers–Sumner–Kearl grade	4.49	A	Very good readability (elementary level)
Paragraph count	74	A	Indicates adequate segmentation for readability
Sentence count	95	A	Balanced sentence structure

[Table/Fig-7]: Readability scores and rating of the Patient Information Leaflet (PIL).

DISCUSSION

The present study evaluated the reliability and overall usefulness of the PIL developed for individuals with breast cancer and for raising public awareness. To enhance its content, a section highlighting the psychological and emotional impact of breast cancer was incorporated to support patients’ mental well-being and coping. The findings indicate that the leaflet is well-organised and presents key information in a clear and user-friendly format.

Evaluations from healthcare professionals confirm that the material is accurate, relevant, and aligned with current educational and clinical requirements. These observations suggest that the leaflet can play an important role in supporting patients’ understanding, encouraging active participation in their care, and strengthening breast health literacy. Furthermore, the positive feedback emphasises the value of developing culturally sensitive and easy-to-understand educational tools that can be applied across both clinical practice and community health programmes.

The Breast Cancer Information Leaflet underwent a comprehensive evaluation using a structured 10-item questionnaire that assessed content clarity and completeness, relevance and practical usefulness, language and presentation, and psychological impact, with overall quality on a 5-point Likert scale. The review was conducted by a panel of 60 multidisciplinary experts—including professionals from Pharmacy Practice- 22 (33.7%), General Medicine- 14 (23.3%), Onco-Pharmacy- 12 (20%), Medical Oncology- 7 (11.7%), and Clinical Research- 5 (8.3%)—ensuring a robust assessment process. This approach goes beyond many previously published evaluations of patient education materials, which often focus solely on readability, such as the study by Beaver K and Luker K. The high scores across all domains demonstrated strong internal consistency, highlighting the leaflet’s clarity, relevance, and practical usefulness for patient education [8].

The internal consistency of the breast cancer information leaflet was assessed using Cronbach’s alpha, which yielded a value of 0.870 across 10 items, indicating a high level of reliability. This finding suggests that the items consistently measure the same underlying concept and are interpreted coherently by respondents. A Cronbach’s alpha above 0.8 is generally considered indicative of good reliability, reinforcing the stability and dependability of the leaflet as an assessment tool. When compared with similar instruments reported in the literature, the current study findings are comparable or even slightly higher. For example, Bu X et al., reported a Cronbach’s alpha of 0.86 for a 15-item breast cancer stigma scale in China [9]. Similarly, Hu W et al., found a Cronbach’s alpha of 0.938 in a validation study of a breast cancer stress scale among patients [10]. Additionally, Noman S et al., reported internal consistency values ranging from 0.76 to 0.87 for different subscales in the adaptation of a screening-beliefs questionnaire among Yemeni women in Malaysia [11]. These comparisons indicate that the breast cancer information leaflet demonstrates reliability on par with established breast cancer-related instruments.

The present study assessed the content validity of a breast cancer information leaflet using the CVI. The findings indicate a high level of agreement among experts regarding the material’s relevance and adequacy. The S-CVI/Ave value of 0.91 reflects excellent content validity, suggesting that the leaflet effectively presents essential information in a manner suitable for the intended audience. In addition, all items demonstrated acceptable I-CVI values, indicating that each component of the leaflet was considered appropriate and clearly expressed by the expert panel. These findings are consistent with established methodological recommendations. According to Polit DF and Beck CT, an S-CVI/Ave value of 0.90 or higher is considered indicative of excellent content validity, while item-level values above 0.78 are regarded as acceptable when evaluated by experts. This supports the interpretation that the leaflet meets standard criteria for content validation [12]. Similarly, Lynn MR emphasised the importance of expert agreement in determining content validity and proposed minimum acceptable values for I-CVI based on the number of experts involved. The results of the present study align with these recommendations, as all items exceeded the suggested threshold, indicating that no revisions or deletions were necessary [13]. Comparable findings have been reported in previous studies by Polit DF and Beck CT involving the development of educational

and healthcare-related materials. For instance, validation studies of patient education tools have reported S-CVI values ranging from 0.80 to 0.95, reflecting good to excellent agreement among experts and supporting the usability of such materials in practice [14].

The high level of expert agreement may be attributed to the clarity, structure, and relevance of the leaflet content, as well-designed materials tailored to the target population tend to achieve better validity outcomes. In breast cancer education, clear and accurate information is crucial for supporting early detection and informed decision-making. Although the findings demonstrate excellent content validity, this represents only one aspect of evaluation; further assessment of readability and effectiveness among the target population is recommended. Overall, the results align with existing evidence and indicate that the leaflet is a valid and suitable educational resource for use in both clinical and community settings.

Readability was assessed using the Readable® readability assessment tool [15]. The readability findings indicate that the PIL is crafted at a level that can be easily understood by the general public. The Flesch Reading Ease score of 65.21 places the leaflet in the “fairly easy” category, demonstrating that the language is straightforward and approachable. Similarly, the Flesch–Kincaid Grade Level of 5.53 and the Gunning Fog Index of 6.03 suggest that individuals with a 5th to 6th grade reading ability can comprehend the content without difficulty. These key indicators align with established recommendations for patient information materials, which advocate for the use of clear, uncomplicated language to support readers with varying literacy skills. The use of simple vocabulary and short sentence structures may also help improve accessibility for non native English speakers and individuals with limited health literacy. In addition, the well-organised structure—reflected through balanced sentence length and appropriate paragraph division—enhances the overall clarity of the leaflet, making the information easier to follow and retain. These findings are consistent with health communication and literacy guidelines, which emphasise that patient education materials should employ clear, simple language to ensure accessibility for individuals with diverse literacy levels. Notably, the readability of the current study leaflet compares favourably with previously reported studies. For example, Suhaj A et al., developed a leaflet for patients with Chronic Obstructive Pulmonary Disease (COPD) that achieved a Flesch Reading Ease score of 68.3 and a Flesch–Kincaid Grade Level of 7.4, indicating “fairly easy” readability [16]. In contrast, a study by Gu JZ et al., which analysed patient information materials from multiple cancer-related websites (including breast cancer), reported an average grade level of 11.81 with a Flesch Reading Ease score of 46.9, suggesting much more challenging reading difficulty [17].

The study findings suggest that the breast cancer information leaflet is a clear, reliable, and practical educational tool for both clinical and community use. Its strong validity, consistency, and readability support its role in improving patient understanding, improving accessibility of breast cancer information, and may support informed participation in care. By addressing gaps in patient-centred communication, it also contributes to better health literacy across diverse populations. Owing to its simple and accessible format, the leaflet can be widely used in awareness programmes, with future scope for evaluation in different populations and adaptation into regional languages and digital formats to enhance its reach.

Limitation(s)

Some limitations should be acknowledged in this study. The evaluation of the PIL was performed only by healthcare professionals and did not include feedback from patients or the general population. In addition, a large proportion of the validators were from the same Institution, which may influence the objectivity of the review. The

study mainly focused on assessing the reliability and readability of the leaflet and did not examine its effect on patient understanding, treatment adherence, or clinical outcomes. Moreover, the leaflet was developed and validated within a single setting and in one language, which may restrict its applicability to wider and more diverse populations.

CONCLUSION(S)

The present study developed and validated a clear, reliable, and accessible PIL for breast cancer education. The PIL's strong internal consistency and high readability indicate that it is well-suited for use in both clinical and community settings. By presenting accurate and easy-to-understand information, the leaflet can support patient engagement and enhance breast cancer awareness. Future research involving direct patient feedback and broader validation will help strengthen its effectiveness and real-world impact.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Dec 13, 2025
- Manual Googling: Apr 06, 2026
- iThenticate Software: Apr 08, 2026 (3%)

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- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

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