

DOI: 10.4274/ijca.2026.27146

Int J Cardiovasc Acad 2026;12(2):109-113

Readability Assessment of Patient Information Leaflets for Commonly Used Cardiovascular Drugs

Halil Siner, Mehmet Gürler, Ramazan Anıl Eşki, Uğur Aksu

Department of Cardiology, Afyonkarahisar Health Sciences University Faculty of Medicine, Afyonkarahisar, Türkiye

Abstract

Background and Aim: Adequate comprehension of drug information leaflets is essential for safe medication use, particularly in cardiology where elderly patients and polypharmacy are common. This study evaluated the readability of patient information leaflets for commonly used cardiovascular drugs in Türkiye.

Materials and Methods: Instructions for use (IFU) and short product information (SPI) sections of 28 cardiovascular drugs (10 NOACs, 9 antiarrhythmics, and 9 antiplatelets) were analyzed using two validated Turkish readability formulas: Ateşman, Bezirci and Yılmaz. Structural text parameters were also quantified.

Results: SPI sections contained significantly higher word, sentence, and character counts than IFU sections ($P < 0.001$). Despite these differences, overall Ateşman readability scores did not differ significantly between IFU and SPI. However, SPI sections of antiarrhythmic drugs demonstrated significantly lower readability and required higher estimated educational levels compared with their IFU counterparts ($P < 0.05$).

Conclusion: The readability of cardiovascular drug leaflets, particularly SPI sections of antiarrhythmic medications, may exceed the educational level of a substantial proportion of elderly patients. Simplification of written drug information may improve patient understanding and medication safety.

Keywords: Readability, drug leaflets, cardiology, NOAC, antiarrhythmic, antiplatelet, elderly patients, patient education

INTRODUCTION

The readability of patient information leaflets is a key determinant of patients' ability to understand medication instructions, potential adverse effects, and safety precautions. In cardiovascular medicine, where patients are often elderly and exposed to complex treatment regimens, inadequate readability may compromise safe drug use.^[1,2]

Regulatory authorities such as the European Medicines Agency (EMA) emphasize that written drug information should be

understandable to the general population and recommend readability testing using real users. However, formula-based readability indices remain widely used as objective screening tools.^[3,4]

This study aimed to evaluate the readability of instructions for use (IFU) and short product information (SPI) sections of commonly prescribed cardiovascular drugs in Türkiye and to estimate the educational level required for adequate comprehension.

To cite this article: Siner H, Gürler M, Eşki RA, Aksu U. Readability assessment of patient information leaflets for commonly used cardiovascular drugs. Int J Cardiovasc Acad. 2026;12(2):109-113



Address for Correspondence: Halil Siner MD, Department of Cardiology, Afyonkarahisar Health Sciences University Faculty of Medicine, Afyonkarahisar, Türkiye
E-mail: sinerhalil@outlook.com
ORCID ID: orcid.org/0000-0001-7885-424X

Received: 04.12.2025
Accepted: 12.03.2026
Publication Date: 22.06.2026



©Copyright 2026 Author(s). Published by Galenos Publishing House on behalf of the Cardiovascular Academy Society. Licensed by Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 (CC BY-NC-ND 4.0)

METHODS

Study Design and Drug Selection

This descriptive, cross-sectional study analyzed patient information leaflets of cardiovascular drugs registered on the Turkish Medicines and Medical Devices Agency (TITCK) website at the time of the study. All NOACs and antiplatelet agents were included. For antiarrhythmic drugs, one representative drug was selected for each active substance to ensure coverage across the class.

This study did not involve any human participants, identifiable personal data, biological material, or interventional procedures. The analysis was based solely on publicly available pharmaceutical package inserts/prospectuses. In accordance with national regulations and international guidelines, this type of methodological/document-based research is exempt from ethics committee approval. Therefore, ethics committee approval was not required for this study.

Data Source

IFU and SPI sections were obtained from the official TITCK website.

Readability Assessment

Readability was evaluated using the Ateşman^[5], Bezirci and Yılmaz^[6] formulas, both validated for Turkish texts. Calculations were performed manually by two independent researchers, and discrepancies were resolved by consensus.

- **Ateşman^[5] Formula:** Readability score = $198.825 - (40.175 \times \text{avg. syllables per word}) - (2.610 \times \text{avg. words per sentence})$.
- **Bezirci and Yılmaz^[6] Formula:** Readability score = $\sqrt{\text{OKS} \times [(H3 \times 0.84) + (H4 \times 1.5) + (H5 \times 3.5) + (H6 \times 26.25)]}$ (OKS: Average sentence length, H3-H6: Average number of 3 to ≥ 6 syllable words per sentence).
- **Ateşman^[5] Readability Index:** Scores are interpreted on a 0-100 scale, where 1-29 indicates “very difficult,” 30-49 “difficult,” 50-69 “moderately difficult,” 70-89 “easy,” and 90-100 “very easy.” Although the Ateşman formula may mathematically produce values outside this interval, scores are conventionally interpreted within the 0-100 readability scale.
- **Bezirci and Yılmaz^[6] Formula:** This formula estimates the educational level required for comprehension: 1-8

corresponds to primary education, 9-12 to secondary education, 13-16 to high school, and >16 to academic education.

Calculations were performed manually by two independent researchers. Discrepancies between the two evaluations were reviewed jointly and resolved by consensus. Although inter-rater agreement statistics were not formally calculated, the formula-based nature of the readability indices ensured objective and reproducible measurements.

Statistical Analysis

Normality of continuous variables was assessed using the Shapiro-Wilk test. IFU and SPI sections belonging to the same drug were compared using paired-sample t-tests, as these sections represent matched textual components of the same leaflet. Data are presented as mean \pm standard deviation.

Given the exploratory nature of the study and the fixed number of available drug leaflets, no a priori power analysis was performed. Statistical significance was set at $P < 0.05$. Analyses were conducted using SPSS version 27.0 (IBM Corp., Armonk, NY, USA).

RESULTS

SPI sections demonstrated significantly higher word counts, sentence numbers, and character counts compared with IFU sections (all $P < 0.001$). Specifically, the mean word count was markedly higher in SPI sections than in IFU sections, accompanied by a greater number of sentences and overall text length. Despite these pronounced structural differences, overall Ateşman^[5] readability scores were comparable between IFU and SPI sections, indicating similar general readability levels (Table 1).

When stratified by drug class, distinct patterns emerged. For antiarrhythmic drugs, SPI sections exhibited significantly lower Ateşman^[5] readability scores compared with IFU sections (71.5 ± 2.68 vs. 65.6 ± 3.10 ; $P = 0.012$), along with significantly higher estimated educational level requirements (7.44 ± 0.88 vs. 8.78 ± 0.66 ; $P = 0.014$) (Table 2).

In contrast, for NOACs, SPI sections demonstrated higher readability scores compared with IFU sections, whereas no significant differences in readability scores or required educational levels were observed between IFU and SPI sections of antiplatelet drugs.

Table 1. Differences between IFU and SPI

| Variables | IFU | SPI | P-value |
|--|--------------|---------------|--------------|
| Number of words | 2379.2±448 | 7325.8±2666 | 0.001 |
| Number of characters | 185518±3408 | 56730.2±18947 | 0.001 |
| Number of difficult words | 2314.0±439 | 7009.1±2487 | 0.001 |
| Number of short words (<5 characters) | 462.5±107 | 1556±709 | 0.001 |
| Number of characters without spaces | 16168.5±2963 | 49385.6±16290 | 0.001 |
| Number of sentences | 391.0±64 | 1311.8±467 | 0.001 |
| Number of paragraphs | 322.7±55 | 1022.4±389 | 0.001 |
| Mean word length | 2.76±0.05 | 2.78±0.15 | 0.754 |
| Average sentence length | 6.07±0.41 | 5.56±0.44 | 0.001 |
| Ateşman ^[5] readability index | 72±1.93 | 72.43±5.59 | 0.464 |
| Readability level | 7.21±0.63 | 7.57±1.06 | 0.132 |

IFU: Instructions for use, SPI: Short product information

Table 2. Readability index and levels of cardiac drug groups according to IFU and SPI

| | IFU | | SPI | | P-value | |
|-----------------|--|-------------------|--|-------------------|--|-------------------|
| | Ateşman ^[5] readability index | Readability level | Ateşman ^[5] readability index | Readability level | Ateşman ^[5] readability index | Readability level |
| NOAC | 72.15±1.62 | 7.15±0.55 | 77.09±1.59 | 6.85±0.55 | 0.001 | 0.317 |
| Anti-platelet | 72.6±1.18 | 7.0±0.3 | 72.51±2.91 | 7.33±0.81 | 0.345 | 0.317 |
| Anti-arrhythmic | 71.5±2.68 | 7.44±0.88 | 65.6±3.1 | 8.78±0.66 | 0.012 | 0.014 |

IFU: Instructions for use, SPI: Short product information

DISCUSSION

This study demonstrated that the readability of drug information leaflets used in cardiology is relatively low, potentially limiting patient understanding. Readability metrics offer objective insights into whether a document is likely to be understood by the average patient. Given the pharmacological complexity of cardiovascular drugs and their associated risks, enhancing the clarity of written information is critical for safe medication use.

Our findings align with previous literature indicating that low readability of drug leaflets may not only impede patient comprehension but also heighten anxiety and reduce adherence.^[7,8] This is especially pertinent for elderly or polymedicated individuals, who often face greater difficulty in interpreting medical content due to age-related cognitive decline, visual impairment, and limited health literacy.

In a national survey conducted in Türkiye involving 1,944 participants, 28.2% were taking one medication, while 17.3% were taking five or more.^[9] Polypharmacy, particularly in elderly populations with low educational attainment, poses a significant barrier to safe and effective drug use.^[10,11] According to Turkish Statistical Institute data, only a small proportion of elderly individuals have completed higher education, whereas nearly half have only primary-level education.^[12] Given that

most drug leaflets in the present study required an estimated education level corresponding to the 7th-8th grade for adequate comprehension, these findings raise important concerns regarding accessibility, patient autonomy, and medication safety.

Similar findings have been reported in recent international studies evaluating the readability of patient information leaflets and other health-related materials. A large systematic overview of readability research covering more than 29,000 health information materials across 438 studies found that most patient education documents exceed the recommended sixth-to-eighth grade reading level required for the general population.^[13] In addition, recent investigations of medication leaflets and digital medicine information systems have demonstrated that complex terminology and long sentence structures remain common, potentially limiting patient comprehension and safe medication use.^[14] Furthermore, contemporary studies evaluating the readability of drug leaflets in different therapeutic areas have reported that many materials still require educational levels above those of a considerable proportion of patients.^[15] Taken together, these findings suggest that limited readability of medication information leaflets represents a persistent and global challenge rather than a country-specific issue.

Furthermore, although the EMA recommends user-based readability testing, most drug information leaflets continue to be evaluated primarily through formula-based indices. While such indices provide standardized and reproducible assessments of textual complexity, they do not capture real-world patient comprehension, contextual understanding, or behavioral outcomes. Therefore, the present results should be interpreted as indicators of potential difficulty rather than direct measures of patient understanding.

An additional noteworthy finding of this study is the significantly lower readability observed in the SPI sections of antiarrhythmic medications. Given that patients often rely on SPI due to its easier accessibility and condensed format, reduced readability in this section may paradoxically increase the risk of misunderstanding, particularly for drugs with narrow therapeutic windows and potentially serious adverse effects. This highlights the need for targeted revision of SPI texts, especially for high-risk cardiovascular medications.

Taken together, these findings underscore the importance of adapting written drug information to the needs of elderly and low-literacy populations. Simplifying sentence structure, reducing medical jargon, and incorporating patient-centered design principles may improve the usability of drug leaflets. Future studies should combine readability assessments with user-testing approaches to better evaluate how revised leaflets influence patient understanding, adherence, and clinical outcomes.

Study Limitations

Several limitations should be acknowledged. First, the study relied solely on formula-based readability indices and did not include user testing or direct assessment of patient comprehension. Second, visual and graphical elements of leaflets were not evaluated. Third, selection of representative antiarrhythmic drugs may introduce selection bias. Finally, inter-rater reliability statistics were not calculated for manual measurements.

CONCLUSION

In conclusion, the readability of patient information leaflets for cardiovascular drugs—particularly the SPI sections of antiarrhythmic agents—may exceed the educational level of a considerable proportion of elderly patients. This mismatch between text complexity and patient literacy may compromise medication safety and informed decision-making. Regulatory authorities and pharmaceutical manufacturers should consider implementing standardized readability thresholds, simplifying technical terminology, and incorporating user-testing procedures during leaflet development. Such measures may enhance patient comprehension, improve adherence, and

ultimately contribute to safer medication use in cardiovascular care.

Ethics

Ethics Committee Approval: This study did not involve any human participants, identifiable personal data, biological material, or interventional procedures. The analysis was based solely on publicly available pharmaceutical package inserts/prospectuses. In accordance with national regulations and international guidelines, this type of methodological/document-based research is exempt from ethics committee approval. Therefore, ethics committee approval was not required for this study.

Informed Consent: Patient informed consent was waived because the study did not involve human participants, animal subjects, or identifiable personal data.

Footnotes

Authorship Contributions

Surgical and Medical Practices: H.S., Concept: M.G., Design: H.S., R.A.E., Data Collection or Processing: M.G., U.A., Analysis or Interpretation: H.S., Literature Search: M.G., Writing: U.A.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

REFERENCES

1. Pander Maat H, Lentz L. Improving the usability of patient information leaflets. *Patient Educ Couns*. 2010;80:113-9.
2. March Cerdá JC, Prieto Rodríguez MA, Ruiz Azarola A, Simón Lorda P, Barrio Cantalejo I, Danet A. Mejora de la información sanitaria contenida en los prospectos de los medicamentos: expectativas de pacientes y de profesionales sanitarios [Quality improvement of health information included in drug information leaflets. Patient and health professional expectations]. *Aten Primaria*. 2010;42:22-7. Spanish.
3. European Commission. Guideline on the readability of the labelling and package leaflet of medicinal products for human use. Revision 1. Brussels: European Commission; 2009 Jan 12 [cited 2025 Nov 5]. Available from: https://health.ec.europa.eu/system/files/2016-11/2009_01_12_readability_guideline_final_en_0.pdf
4. Gazmararian JA, Williams MV, Peel J, Baker DW. Health literacy and knowledge of chronic disease. *Patient Educ Couns*. 2003;51:267-75.
5. Ateşman E. Türkçede okunabilirliğin ölçülmesi. *Dil Dergisi*. 1997;58:71-4.
6. Bezirci B, Yılmaz AE. Metinlerin okunabilirliğinin ölçülmesi üzerine bir yazılım kütüphanesi ve Türkçe için yeni bir okunabilirlik ölçütü [A software library for measurement of readability of texts and a new readability metric for Turkish]. *DEUFMD*. 2010;12:49-62. Turkish.
7. Laçiner K, Özdin S. Readability levels of package leaflets of psychotropic drugs. *Turk J Clin Psychiatry*. 2024;27:161-8.

8. Ay İE, Duranoğlu Y. Göz damlası prospektüslerinin okunabilirlik düzeyinin değerlendirilmesi [An evaluation of the readability of package inserts of eye drops]. *Anadolu Klin.* 2022;27:55-9. Turkish.
9. Arslan Ş, Atalay A, GökçeKutsal Y. Yaşlılarda ilaç tüketimi [Drug use in elderly]. *Türk Geriatri Derg.* 2000;3:56-60. Turkish.
10. Nolan PE Jr, Marcus FI. Cardiovascular drug use in the elderly. *Am J Geriatr Cardiol.* 2000;9:127-9.
11. Secoli SR. Polifarmácia: interações e reações adversas no uso de medicamentos por idosos [Polypharmacy: interaction and adverse reactions in the use of drugs by elderly people]. *Rev Bras Enferm.* 2010;63:136-40. Portuguese.
12. Türkiye İstatistik Kurumu (TÜİK). İstatistiklerle Yaşlılar, 2024 [Internet]. Ankara: TÜİK; 2024 [cited 2025 April 14]. Available from: <https://data.tuik.gov.tr/Bulten/Index?p=Elderly-Statistics-2024-54079>
13. Okuhara T, Furukawa E, Okada H, Yokota R, Kiuchi T. Readability of written information for patients across 30 years: a systematic review of systematic reviews. *Patient Educ Couns.* 2025;135:108656.
14. Yang J, Kwon K. Assessing readability and usability of electronic medicine package leaflets in South Korea: a mixed-methods study. *Drug Healthc Patient Saf.* 2025;17:181-96.
15. Altınsoy M. How much understandable of patient information leaflets?. *EJCM.* 2024;12:12-6.