

ANTIPLATELET VE ANTIKOAGÜLAN İLAÇ PROSPEKTÜSLERİNİN OKUNABİLİRLİĞİNİN DEĞERLENDİRİLMESİ

EVALUATION OF THE READABILITY OF ANTIPLATELET AND ANTICOAGULANT MEDICATIONS PROSPECTUSES

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ÖZET

AMAÇ: Bu çalışmada, kardiyovasküler hastalıkların tedavisinde yaygın olarak reçete edilen antiplatelet ve antikoagülan ilaç prospektüslerinin okunabilirlik düzeyleri değerlendirildi.

GEREÇ VE YÖNTEM: Türkiye İlaç Rehberi'nden ulaşılan 13 ilaca ait prospektüs (KÜB-KT) analiz edilerek, Ateşman, Bezirci-Yılmaz ve Çetinkaya-Uzun okunabilirlik formülleri kullanılarak değerlendirme yapıldı. Sözcük sayısı, cümle uzunluğu ve hece sayısı gibi metinsel ölçütler analiz edildi.

BULGULAR: Ateşman formülüne göre ortalama okunabilirlik skoru 71,45 olup "kolay" düzeyde bir metne işaret etmektedir. Ancak Bezirci-Yılmaz ve Çetinkaya-Uzun formülleri, metinlerin anlaşılabilirliği için en az lise düzeyinde eğitim gerektirdiğini göstermiştir. Çok heceli sözcüklerin ve karmaşık cümle yapılarının sık kullanılması, düşük sağlık okuryazarlığına sahip bireyler için önemli bir engel teşkil etmektedir.

SONUÇ: Antiplatelet ve antikoagülan ilaç prospektüslerinin büyük kısmı, hasta materyalleri için önerilen okunabilirlik düzeyinin üzerindedir. Bu durum hasta anlayışını, tedaviye uyumu ve güvenliği olumsuz etkileyebilir. Prospektüslerin sadeleştirilmesi için sağlık okuryazarlığı uzmanları ile iş birliği yapılması ve düzenleyici önlemler alınması gerekmektedir.

ANAHTAR KELİMELEER: Okunabilirlik, Antiplatelet ve antikoagülan ilaçlar, Web tabanlı sağlık bilgisi.

ABSTRACT

OBJECTIVE: This study aimed to evaluate the readability of prospectuses (Patient Information Leaflets) for antiplatelet and anticoagulant medications, which are widely prescribed for cardiovascular conditions.

MATERIAL AND METHODS: A total of 13 drug prospectuses (6 anticoagulants, 7 antiplatelets) were retrieved from the Turkish Drug Guide. Readability scores were calculated using the Ateşman, Bezirci-Yılmaz, and Çetinkaya-Uzun formulas. Textual metrics such as word count, sentence length, and syllable count were analyzed.

RESULTS: According to the Ateşman formula, the average readability score was 71.45, indicating an "easy" level. However, the Bezirci-Yılmaz and Çetinkaya-Uzun scores revealed that these texts require at least a high school education level to comprehend. The high proportion of multi-syllabic words and complex sentence structures in the prospectuses limits accessibility for patients with low health literacy.

CONCLUSIONS: Most antiplatelet and anticoagulant medication prospectuses exceed the recommended readability level for patient materials. This may negatively impact patient understanding, medication adherence, and safety. The results underscore the need for regulatory oversight and collaboration with health literacy experts to improve the design and clarity of drug information materials.

KEYWORDS: Readability, Antiplatelet and anticoagulant medications, Web-based health information.

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INTRODUCTION

Antithrombotic drugs are pharmacological agents that inhibit blood clot formation and/or promote the breakdown of existing thrombi. Based on their mode of action, they are categorized into three classes: i. Anticoagulants, ii. Antiplatelet agents, iii. Fibrinolytics (thrombolytics). Physiologically, hemostasis refers to the formation of clots outside the blood vessel to stop bleeding after vascular injury. In contrast, thrombosis is a pathological condition characterized by clot formation within the vessel, often without any injury. Although both processes involve similar pathways, thrombosis is undesired and can lead to serious clinical consequences such as myocardial infarction, stroke, or pulmonary embolism. Antithrombotic therapies aim to prevent or treat thrombotic events, but by interfering with normal clotting mechanisms, they also carry a risk of bleeding and may impair physiological hemostasis (1). For prevention of adverse effects, appropriate usage of drugs are so important. Education of patients and reading of prospectus related with medication usage are main way for prevention of adverse effects. Nowadays, medical professionals do not have enough time for detailed inform of patient about medications usage and adverse effects. In this point, prospectuses another word Patient Information Leaflets of medications have an important role. But, readability of medication prospectuses are as important as content and rationale of prospectuses. Patients which have different education levels should understand especially usage, posology and adverse effects of medications when they read prospectuses. Readability is briefly expressed as the level of understanding of texts by readers. The readability formula prepared by Vogel and Washburne in 1928 is the first formula prepared in this field. After this formula, scientists from different fields prepared formulas by using different variables. The first study in this field at Turkey was carried out by Ateşman in 1997 (2). There is a positive correlation between readability and reading amount of a text. Texts which are difficult to read are not read by readers.

But, texts which are easy to read are attract the attention of readers. For that reason, readability level of a text directly effect the effectiveness and efficiency of the text. In this context, as for other texts in the books, prospectus of a medication must be appropriate to the level of the reader along with the qualities that they have.

In this study, it was aimed to measure the readability level of the prospectuses of anticoagulant and antiplatelet medications that are commonly used for cardiovascular diseases which are frequently seen in most patients due to increased level of metabolic diseases. This study did not aim to compare prospectus readability across different indication groups. Instead, the inclusion of prospectuses from various indications was intended to ensure broader representation and generalizability.

MATERIALS AND METHODS

The list of all active anticoagulants and antiplatelets available in pharmacies was taken from the current webpage of the Turkish Drug Guide by author (3). The prospectuses of 6 anticoagulant medications and 7 antiplatelet medications were transferred to the readability calculation engine at "<https://www.webfx.com/tools/read-able/>" by mean of copying. Page count, sentence count, word count, syllable count, average sentence length and average word length of each drug prospectus were calculated. By using these parameters, the readability values were calculated using the formulas derived by Ateşman, Bezirci-Yılmaz and Çetinkaya-Uzun. This study evaluated drug prospectuses available on the internet. Since no human or animal subjects were used, no approval or ethics committee is required for such articles.

The Ateşman readability formula:

Readability score: $198.825 - (40.175 \times \text{word length}) - (2.610 \times \text{sentence length})$. Word length is calculated by division total syllable count to total word count and sentence length is calculated by division of total words to total sentences. A readability score of 0-100 is obtained. As the score increased, the readability of the text increases (2) (**Table 1**).

Table 1: Readability Levels in Ateşman's Readability Formula (Ateşman, 1997)

Readability Score	Readability Level
90-100	Very Easy
70-89	Easy
50-69	Moderate
30-49	Difficult
1-29	Very Difficult

The Çetinkaya-Uzun readability formula:

Readability score: $118.823 - (25.987 \times \text{average word length}) - (0.971 \times \text{average sentence length})$. The second formula developed for Turkish reading materials is the Çetinkaya-Uzun Readability Formula. In general, the two variables of readability formulas, the average word and sentence length, had a significant relationship with the extraction score, and the readability equation above was obtained by applying multiple linear regression analysis (**Table 2**) (2).

Table 2: Readability Levels in the Çetinkaya-Uzun Formula (Çetinkaya, 2010)

Readability Score	Readability Level	Education Level
0-34	Insufficient Reading Level	10, 11 ve 12. Sınıf
35-50	Instructional Reading Level	8 ve 9. Sınıf
51+	Independent Reading Level	5, 6 ve 7. Sınıf

The Bezirci-Yılmaz readability formula:

Readability score: $\sqrt{\text{Average word length} \times ((H3 \times 0.84) + (H4 \times 1.5) + (H5 \times 3.5) + (H6 \times 26.25))}$. This score was developed for Turkish texts. It is based on length of sentences, words, syllable of words which are found in a text. Readability values are created and classified by counting the average number of words with three, four, five, six or more syllables in a sentence. H3: Average number of three-syllable words in a sentence, H4: Average number of four-syllable words in a sentence, H5: Average number of five-syllable words in a sentence, H6: Average number of six-syllable words in a sentence (**Table 3**) (2).

Table 3: Readability Levels According to Bezirci-Yılmaz Formula (Bezirci and Yılmaz 2010)

Readability Score	Education Level
1-8	Elementary School
9-12	High School
13-16	Bachelor's Degree
16+	Higher education

Statistical Analysis

The SPSS 20 software was used for data analysis. Frequency and percentages were used to represent categorical data. The mean and standard deviation were used to represent numerical data.

RESULTS

The readability evaluation of 13 antiplatelet and anticoagulant medication prospectuses was conducted using various metrics.

The mean word count across the prospectuses was 2155.33 ± 449.016 . The average number of sentences per document was 352.08 ± 74.394 , with an average sentence length of 6.0417 ± 0.29064 words, indicating variability in sentence construction across the analyzed documents.

The mean syllable count was 7639.58 ± 9294.465 , while the average number of characters per document was 14574.33 ± 6585.034 .

These metrics reflect the complexity of the language used in the documents. The average number of difficult words (words with more than three syllables) was $2007.17 \pm 657,098$, highlighting the frequent use of technical and specialized vocabulary. The total text length across the prospectuses averaged $8,335.33 \pm 1,670$ characters, further illustrating the extensive nature of these materials (**Table 4**).

Table 4: Descriptive statistics summarizing the key findings are presented

	Word count	Number of characters	Difficult words	Short words	Number of characters without spaces	Sentence count	Number of paragraphs	Average Word length	average sentence length	syllable count	page count
Mean	2155.33	14574.33	2007.17	1121.50	14020.83	352.08	279.15	2.7783	6.0417	7639.58	8.33
Std. Deviation	449.016	6585.034	657.098	2442.853	5030.319	74.394	98.156	.04282	.29064	9294.465	1.670

The average number of long sentences (defined as sentences with more than 20 words) was 23.63 ± 1.249 , suggesting that the majority of the sentences are concise but a notable portion includes detailed explanations.

The average readability score for the prospectuses was calculated as 71.45 ± 1.99 , indicating that the materials require a moderate level of literacy to comprehend (**Table 5**).

Table 5: Different mean readability indexes of antiplatelets and anticoagulants prospectuses

	Ateşman READABILITY INDEX	Bezirci Yılmaz READABILITY INDEX	Çetinkaya Uzun READABILITY INDEX
Mean	71.450	23.63375	21.78742
Std. Deviation	1.9902	1.249475	2.446052

These results suggest that antiplatelet and anticoagulant medication prospectuses generally feature technical language, moderate sentence complexity, and readability levels that may pose challenges for patients with lower literacy levels. The findings underscore the importance of revising such documents to enhance accessibility for a broader audience.

Further research could focus on comparing these findings with international readability standards to identify specific areas for improvement in prospectus design.

DISCUSSION

The findings of this study indicate that the readability levels of antiplatelet and anticoagulant medication prospectuses are generally above the recommended thresholds for patient comprehension. Readability assessments revealed that most package leaflets exceed the recommended readability level for health-related materials, posing a potential barrier for patients with low health literacy. This is consistent with previous studies evaluating the readability of pharmaceutical package leaflets and other patient-directed medication information (4).

A major concern arising from these findings is the potential impact on medication adherence and patient safety. Prior research has highlighted that inadequate readability in drug safety materials may contribute to preventable medication errors (5). Given that patients rely on package leaflets for crucial information regarding drug administration, contraindications, and side effects, poor readability could lead to misunderstandings, improper usage,

or even non-adherence to prescribed treatment regimens. In this regard, the study aligns with existing literature suggesting that patient education materials often fall short in terms of understandability and actionability (6).

The results also align with broader trends observed in studies on medication package leaflets. For instance, research on biosimilar medications has demonstrated that package leaflets tend to be complex, often surpassing the recommended readability scores (7). This suggests that the problem is not limited to a single class of drugs but extends across multiple therapeutic categories. Similarly, studies examining readability in other patient education materials have found that even when information is deemed understandable, it may not always be actionable, reducing its practical value (8).

Another important aspect to consider is the regulatory framework governing the design of package leaflets. While the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) provide guidelines on improving the readability of medical documents, our findings indicate that adherence to these recommendations is inconsistent (9). This discrepancy highlights the need for stricter implementation of plain language principles and greater involvement of health literacy experts in the design of patient information leaflets.

Addressing these readability challenges requires a multifaceted approach. First, regulatory agencies should enforce stricter readability standards and conduct systematic reviews of patient information leaflets to ensure compliance. Second, pharmaceutical companies should collaborate with health literacy experts and patient advocacy groups to develop materials that are both comprehensible and actionable. Finally, healthcare professionals should play a more active role in bridging the gap between complex medical information and patient understanding by providing verbal explanations and supplementary materials when necessary.

This study has several limitations. The readability assessment was based on objective readability formulas, which do not account for factors such as patient familiarity with medical termi-

nology or cultural differences in comprehension. Future research should incorporate qualitative assessments, such as patient interviews or focus groups, to evaluate the real-world understandability of these materials. Additionally, studies comparing the readability of package leaflets across different regulatory regions may provide further insights into global best practices for improving patient comprehension. A major limitation of this study is that it did not aim to compare prospectus readability across different indication groups. Rather, prospectuses from various indications were included to achieve broader representation and enhance generalizability, which may limit the ability to draw indication-specific conclusions.

Overall, the findings reinforce the urgent need to improve the readability of antiplatelet and anticoagulant medication prospectuses. Poor readability remains a significant barrier to patient comprehension, potentially affecting medication adherence and health outcomes. By integrating evidence-based readability standards into pharmaceutical communication strategies, stakeholders can enhance patient safety and empower individuals to make informed decisions regarding their treatments.

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