How Much Understandable of Patient Information Leaflets?

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Abstract

Objectives: Patient information leaflets play a crucial role in educating patients about their conditions and in sharing the responsibility for treatment and follow-up with their physicians. Purpose of this study indentifying the readability level of prospectuses according to national education system of our country and comparing the readability ratios among each other.

Materials and Methods: Fifteen oral anticoagulants and their equivalents, various readability analyses were performed, including the Gunning Fog Index (FOG), Automated Readability Index (ARI), Flesch-Kincaid Readability Analysis, Flesch Reading Ease (FRE), Ateşman, Coleman-Liau, and Powers-Sumner-Kearl (PSK).

Results: The metrics we extracted were calculated according to the formulas developed for criteria, such as Simple Measure of Gobbledygook, FOG, ARI, Flesch-Kincaid, FRE, Ateşman, Coleman-Liau, and PSK which are primarily scientifically accepted and have been developed to understand readability. According to the Ateşman scale, the average readability value of patient information leaflets is 53.2. It is observed that the readability value of the patient information leaflets for 15 oral anticoagulant drugs is between 50 and 59 on the Ateşman scale. Leaflets are moderately difficult to understand and requires high school education. IN terms of comparison patient information forms of Eliquis 2.5/5 mg and Pradaxa 150 mg were easier to read, unlike Pradaxa 110 mg.

Conclusion: All the 15 oral anticogulants' prospectuses requires simplifying an education level that equivalent to the average schooling years in Turkey, which is 6 years, instead of a high school-level education.

Keywords: Readability, prospectuses, oral anticoagulants, adverse effects

Introduction

Patient information leaflets play a crucial role in educating patients about their conditions and in sharing the responsibility for treatment and follow-up with their physicians. This is especially critical for drugs with potentially fatal adverse effects that are used lifelong, such as oral anticoagulants (OACs). The importance of patient information leaflets and their comprehensibility to patients becomes increasingly vital in these cases[1]. In our study, we tested the readability of the prospectuses for OACs.

Materials and Methods

Within the scope of the research, 15 Turkish prospectuses for various mg types of the drugs Eliquis, Lixina, Pradaxa, Rivoksar, Rovaran, Venomia, and Xarelto were analyzed. These drugs are most frequently used in various branches, such as cardiology, neurology, pulmonology, and cardiovascular surgery, primarily for conditions like atrial fibrillation and vascular thromboembolism. To measure the intelligibility levels of 15 OACs and their equivalents, various readability analyses were performed, including the FOG, Automated Readability Index (ARI), Flesch-Kincaid Readability Analysis, Flesch Reading Ease (FRE), Ateşman, Coleman-Liau, and Powers-Sumner-Kearl (PSK)[1-4].

These methods and metrics are utilized to assess the readability levels of texts. They facilitate understanding of which age group and educational level the text is suited for and guide authors in crafting texts appropriate for their target audiences. Furthermore, these tools can identify necessary modifications to enhance the clarity of texts. In the package inserts, various text analyses were conducted using tools from general-purpose data and text mining, as well as natural language processing (NLP). The word frequencies in the consent form texts were calculated, and statistical analyses based on N-grams were performed. Additionally, the grammatical structures of the words in the texts were examined using the Part-of-Speech (POS) tagging method. Sentence parser analyses were employed to analyze the relationships between sentences and to identify significant relationships and connections within the texts. Analyses of noun-phrase pairs and topic modeling were also carried out.

Results

This study, conducted using text mining techniques, NLP, and artificial intelligence tools, aimed to enhance drug effectiveness and reduce problems arising from misuse by clearly conveying essential information such as dosage, frequency, and method of use to patients.

For all medication package inserts, readability analyses including FOG, ARI, Flesch-Kincaid Readability Analysis, FRE, Ateşman, Coleman-Liau, and PSK were used to measure their intelligibility levels[2-4]. Various text analyses were performed using tools from general-purpose data, text mining, and NLP. These analyses included calculating word frequencies in the texts, conducting statistical analyses based on N-grams, examining the grammatical structures of words using the POS tagging method[5], analyzing the relationships between sentences using sentence parser analyses, and identifying significant relationships and connections within the texts using noun-phrase pairs analyses and topic modeling.

A language model was developed in order to enhance the readability of the examined package inserts. This model learns the language patterns of pharmaceutical package prospectusus, produces new, more readable and understandable sentences and texts, summarizes the essential points and main ideas of the texts of prospectuses, and emphasizes important information.

To perform readability analyses of the prospectuses, it is necessary to calculate the grammatical features of the texts. For this reason, various metrics such as sentence structure, number of words, letters, characters, syllables, and multisyllabic words were extracted from the consent forms and are presented in the table below.

- Medication
- Number of sentences
- Number of words

- Number of letters
- Number of characters
- Number of syllables
- Number of multisyllabic words
- The metrics we extracted were calculated according to the formulas developed for criteria, such as Simple Measure of Gobbledygook, FOG, ARI, Flesch-Kincaid, FRES, Ateşman, Coleman-Liau, and PSK which are primarily scientifically accepted and have been developed to understand readability. From these calculations, readability values were obtained (Table 1, Figure 1).

Among the criteria shown in the table, the most crucial readability formula developed for Turkish texts was defined by Ateşman. According to the Ateşman scale, the average readability value of patient information leaflets is 53.2. It is observed that the readability value of the patient information leaflets for 15 OAC drugs is between 50 and 59 on the Ateşman scale.

Statistical Analysis

In the prospectuses, N-gram analysis, a text analysis method that calculates the number and distribution of consecutive word groups (N-grams), was also performed. N-gram analysis is used to obtain information, such as word frequency in texts, relationships among words, and grammatical structures. By measuring the frequency of specific word combinations in the text, N-gram analysis allows us to determine which word groups are more frequently used, providing insights into the content of the text and language usage. According to the N-gram results, the phrase "side effects" (128) appears with the highest frequency in the package inserts, indicating that statements about the possible side effects of the relevant drugs are frequently used. The phrases "15 mg" (123) and "once a day" (118) also have high n-gram frequencies, showing that statements providing information about the daily dosage and frequency of drug use are commonly included in the package inserts (Figure 2). Additionally, "blood clot" (102) is another phrase with a high n-gram frequency. The phrase "to your doctor or pharmacist" (82) also has a high frequency, suggesting that the need to consult a doctor or pharmacist when making decisions about drug use is heavily emphasized.

Table 1. Readability values of prospectuses according to various criteria

	SMOG	FOG	ARI	Flessch-Kincaid	FRES	Ateşman	Coleman-Liau	PSK	Readability value
Eliquis 2.5 mg	12.66	15.44	13.55	21.22	-40.01	61.2	34.67	14.78	9.66
Eliquis 5 mg	12.91	15.74	13.71		-40.42	60.12	34.75	14.81	9.93
Lixiana 15 mg	14.24	17.67	16.27	23.91	-55.66	49.44	37.34	14.06	14.32
Lixiana 30 mg	13.89	16.99	15.03	22.65	-47	53.96	35.86	14.58	11.95
Lixiana 60 mg	13.89	16.99	15.03	22.66	-47.07	53.94	35.87	14.57	11.94
Pradaxa 110 mg	14.29	17.05	15.24	22.09	-40.51	54.1	35.54	15.22	12.55
Pradaxa 150 mg	11.38	14.3	12.26		-31.42	70.04	33.52	15.05	7.05
Rivoksar 15 mg	14.62	17.68	17.01	23.52	-50.47	49.07	37.7	14.57	13.48
Rivoksar 20 mg	14.59	17.65	16.98	23.49	-50.38	49.25	37.68	14.57	13.41
Rivoran 15 mg	14.43	17.53	16.71	23.4	-50.49	50.05	37.53	14.5	13.05
Rivoran 20 mg	14.46	17.51	16.75	23.36	-49.89	50	37.5	14.56	13.19
Venomia 15 mg	14.92	18.56	16.8	23.75	-52.75	48.75	37.6	14.37	13.23
Venomia 20 mg	14.92	18.56	16.81	23.76	-52.82	48.72	37.61	14.37	13.23
Xarelto 15 mg	14.47	17.56	16.65	23.43	-50.54	49.84	37.42	14.51	13.15
Xarelto 20 mg	14.45	17.55	16.63	23.42	-50.54	49.97	37.42	14.5	13.08

SMOG: Simple Measure of Gobbledygook, FOG: Gunning Fog Index, ARI: Automated Readability Index, PSK: Powers-Sumner-Kearl
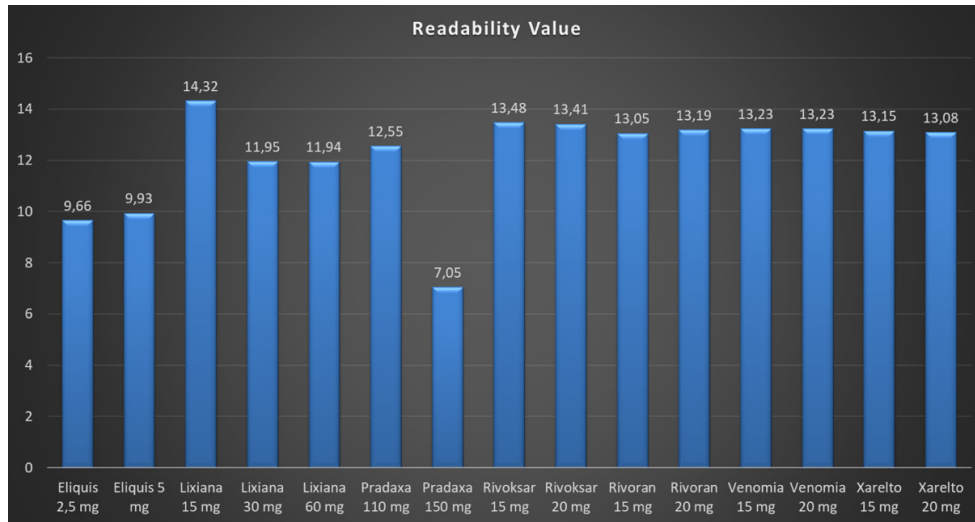
Figure 1. Readability values of patient information leaflets according to various criteria
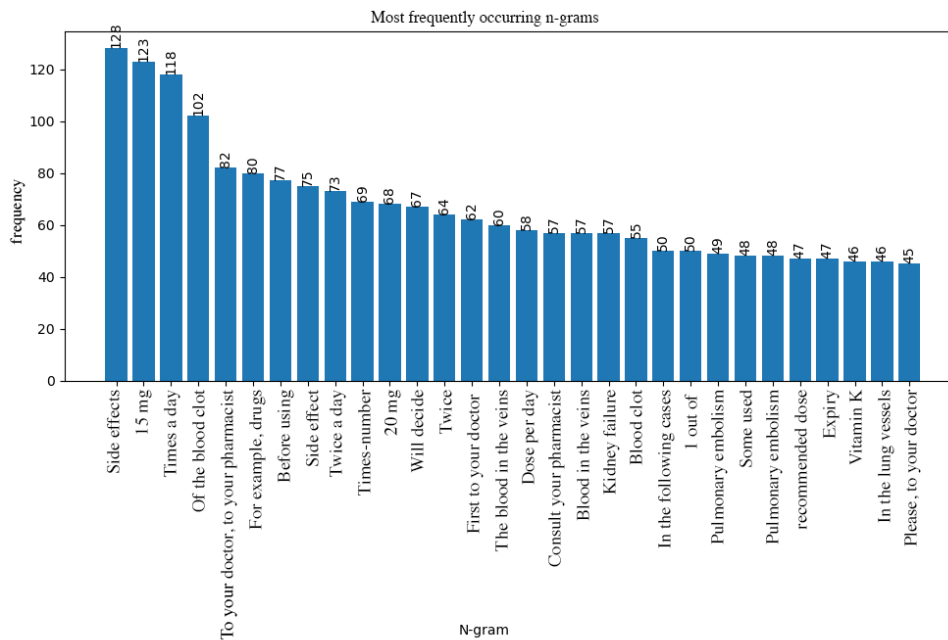

Figure 2. Column graph of the 30 most frequently used n-grams in the package inserts[1]
[1]The vertical elevation of the columns represents the frequency of the n-grams, while the x-axis shows the n-grams, and the y-axis displays the frequencies. In this way, it indicates which n-grams occur most frequently and which ones are less frequent.

Discussion

In this study, the readability levels of OAC drugs were evaluated using readability scales. Furthermore, by employing text mining techniques, NLP, and various artificial intelligence tools, it is aimed to clearly convey information such as dosage, frequency, and method of use to patients, thus enhancing drug effectiveness and reducing problems that may arise from misuse.

Conclusion

As a result of the analysis made on the package inserts of 15 OAC drugs, it was seen that the patient information forms of Eliquis and Pradaxa 150 mg were easier to read, unlike Pradaxa 110 mg.

We recommend simplifying the prospectuses to a level that requires an education equivalent to the average schooling years in Turkey, which is 6 years, instead of a high school-level education[6].

Ethics

Ethics Committee Approval: Ethical approval for the study was received from Ankara Etlik City Hospital Scientific Research Evaluation and Ethics Committee (approval no.: AEŞH-BADEK-2024-139, date: 14.02.2024).

Informed Consent: Informed consent was obtained.

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