

How readable are antihypertensive drug inserts?

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ABSTRACT

Aim: Patients can be protected against possible complications when antihypertensive drugs are regularly and properly used for the treatment of hypertension. The readability of package inserts increases treatment compliance. In the present study, the purpose was to determine the readability level of antihypertensive package inserts.

Materials and Method: A total of 64 commonly used antihypertensive drugs were selected for this study. The readability scores of the package inserts for the selected drugs were calculated according to the Readability Scales developed by Atesman and Bezirci-Yilmaz.

Results: The readability level for the selected package inserts were found to be suitable for an average of 11-12 years of education and high school education level according to the Atesman and Bezirci-Yilmaz Readability Scales, respectively.

Conclusion: When it is considered that the average schooling year in Turkey is 6.5 years, the readability level of antihypertensive package inserts is highly above this level. It is recommended to simplify the package inserts to increase readability and drug compliance and prevent incorrect drug use.

Keywords: Hypertension, package insert, readability level

INTRODUCTION

Hypertension is an important public healthcare issue with increasing prevalence around the world. If untreated, this disease can cause significant mortality and morbidity rates due to heart, brain, kidney, and retina problems (1,2). In terms of first-line treatment, lifestyle changes are recommended to the patients (3,4). The ongoing high blood pressure despite lifestyle changes or due to risk factors (diabetes mellitus (DM), chronic kidney disease (CKD), coronary artery disease (CAD), etc.), antihypertensive treatment is initiated (5). Patients who start the drug treatment may desire to learn more about drug-related side effects, drug use, and dosage by reading the package inserts. As the education level of the patients increases, the rate of reading the prospectus increases (6,7). Some patients stop using the drug or change the drug dose regardless of the physician's knowledge after reading the drug inserts. Therefore, these package inserts must be at an adequate level for patients to understand.

Readability levels are the main evaluation criteria to assess whether the package inserts are understood by the patients (8). The readability level of a text is determined by adopting certain scales proven and reported by scientific studies(9). These scales calculate the readability

score by using various parameters such as the number of sentences in the text, the number of words, and the number of syllables. Accordingly, Atesman (10) and Bezirci-Yilmaz (11) Readability Scales are frequently used for Turkish texts.

In the present study, the purpose was to measure the readability level of antihypertensive package inserts, which are frequently used by patients in Turkey and to determine which age and education level the texts on the package inserts are suitable for.

MATERIAL AND METHOD

The study was conducted according to the decision of the Afyonkarahisar Health Sciences University Clinical Researches Ethics Committee (Date: 05.08.2022, Decision No: 2022/400). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

A total of 64 antihypertensive drugs frequently used by the patients were randomly selected for the study. The readability scores of the package inserts of these drugs were calculated. These drugs were divided into 6 groups which were angiotensin converting enzyme (ACE)

inhibitors/angiotensin receptor blockers (ARB), calcium channel blockers (CCB), beta-blockers, alpha-blockers, diuretics, and combined drugs (drugs that contain more than one antihypertensive group). The mean readability level of these drug groups was evaluated independently and comparatively. When evaluating the readability levels of the package inserts, the titles and the license information at the end were evaluated based on the text on the inserts.

When determining the readability levels, various scales can be used. These scales provide an average score based on parameters such as the number of words in the text, the number of sentences, and the number of letters. The readability levels of the drugs in our study were evaluated by using Ateşman (10) Readability Scale and Bezirci-Yılmaz (11) Readability Scale.

The readability score calculated on the Atesman Readability Scale ranges from “0” to “100”. The scores means that as the score approaches “100”, the readability increased as the score decreases toward “0”, the readability decreases. When calculating Atesmen readability points, the following formula was used.

$$RS=198.825-(40.175 \times X1)-(2.610 \times X2)$$

RS: Readability Score

X1: Total number of syllables/ Total number of words

X2: Total number of words/Total number of sentences

The comparison of Atesman Readability Scores according to educational levels is shown in **Table 1**.

Table 1: The educational status equivalent of the readability score calculated with the Atesman Readability Scale

Readability score	Educational status
90-100	It can be read by anyone who is in the 4th grade of primary school and below.
80-89	It can be read by anyone studying at the 5th or 6th grade level.
70-79	It can be read by anyone studying at the 7th or 8th grade level.
60-69	It can be read by anyone studying at the 9th or 10th grade level.
50-59.	It can be read by anyone studying at the 11th or 12th grade level.
40-49	It can be read by anyone studying at the 13th or 15th grade level.
30-39	It can be read by anyone with an undergraduate degree.
≤29	It can be read by anyone with a graduate degree

For the Bezirci-Yılmaz Readability Scale, a higher score corresponds to a text that is harder read while a lower score corresponds to a text that is easier to read. In calculating the Bezirci-Yılmaz readability score, the following formula was used;

$$RS= \sqrt{AWC \times ((S3 \times 0.84) + (H4 \times 1.5) + (H5 \times 3.5) + (H6 \times 26.25))}$$

RS: Readability Score

AWC: average word count

S3: average number of 3-syllable words

H4: average number of 4-syllable words

H5: Average number of 5-syllable words

H6: Average number of words with 6 or more syllables

The comparison of Bezirci-Yılmaz Readability Scores according to educational levels is shown in **Table 2**.

Table 2: The educational levels equivalent of the readability score calculated with the Bezirci-Yılmaz Readability Scale

Readability score	Educational status
1-8	Primary School
9-12	Secondary School (High School)
13-16	Undergraduate
16+	Academic level education

The computer program that was developed by Bezirci-Yılmaz was used in calculating the readability scores by using these formulas.

Statistical Analysis

The categorical variables were presented as percentage and frequency and the continuous variables were expressed as mean and standard deviation. The ANOVA Test was used for continuous variable comparison between groups. Statistical analyzes were performed with the SPSS 26.0 package program. All presented p values were bidirectional, and p<0.05 values were considered statistically significant.

RESULTS

A total of 64 package inserts were evaluated in the study. The average readability level of these drugs was found 52.58±7.84 according to Atesman Readability Scale and on average, it required 11-12 years of education. According to the Bezirci-Yılmaz Readability Scale, the average readability level was found 11.99±2.35. The corresponding education level was secondary (high school) level on average (**Table-3**)

Table 3: The mean scores of antihypertensive drugs calculated according to the Atesman and Bezirci-Yılmaz Readability Scales and the corresponding education levels

	Number	Minimum	Maximum	Mean (standart deviation)	Educational status
Ateşman	64	37,17	79,61	52,5823±7,84	11-12 years
Bezirci Yılmaz	64	5,14	17,24	11,9905±2,35	Secondary School (High School)

Package inserts were divided into 6 groups which were ACE inhibitors/ARB (n:23), CCB (n:10), beta-blockers (n:10), alpha-blockers (n:3), diuretics (n:4), combined drugs (n:14). Among these drug groups, diuretic group drug inserts were found to be the group that required the highest education level for both Readability Scales. It was found that an undergraduate level of education was required on average for the readability of the drugs in the diuretic drug group.

The average scores and comparisons of the drug groups that were calculated according to the Atesman and Bezirci-Yilmaz Readability Scale are shown in **Figures 1 and 2**. The educational levels corresponding to the mean scores of the drug groups are shown in **Table 4**.

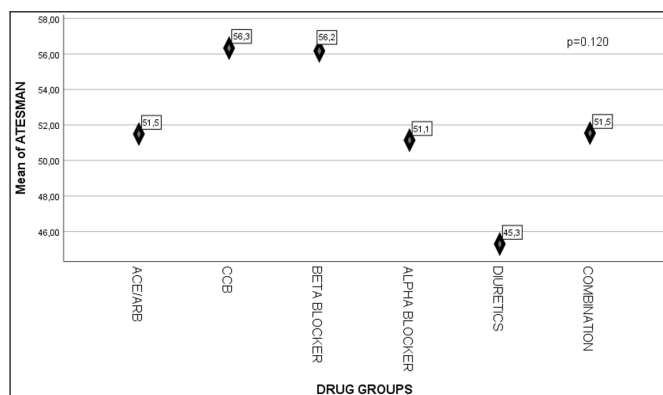


Figure 1: The mean scores of the drug groups according to the Atesman Readability Scale

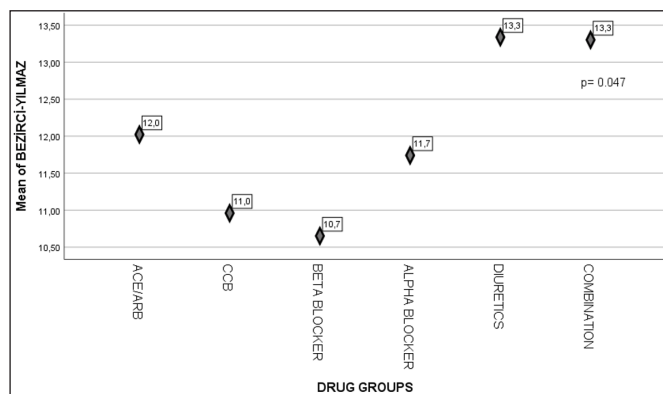


Figure 2: The mean scores of the drug groups according to the Bezirci-Yilmaz Readability Scale

	Bezirci-yilmaz	Atesman
ACE/ARB	Secondary school (high school)	At 11 th or 12 th grade level
CCB	Secondary school (high school)	At 11 th or 12 th grade level
Beta blocker	Secondary school (high school)	At 11 th or 12 th grade level
Alpha blocker	Secondary school (high school)	At 11 th or 12 th grade level
Diuretics	Undergraduate	13 th or 15 th grade level
Combined drugs	Undergraduate	At 11 th or 12 th grade level

DISCUSSION

In this study, the aim was to determine the readability levels of antihypertensive package inserts. According to the Bezirci-Yilmaz and Atesman readability scales, an average high school education is required for the readability of the package inserts. This level is above the schooling level in Turkey. Therefore, we recommend that these drug inserts should be edited in accordance with the schooling year in Turkey. In addition to the text content, the value of a text is also related to how much a text is understandable by the individual who reads the text. The value of the text is determined based on the comprehension level of the individual. Throughout the historical process, various Readability Scales were developed in the world since the 1950s to determine the readability of texts. The Flesch Reading Ease Score (FRES) and the Gunning Fog Index are some of the important readability scales (12,13). These scales determined the readability level by using the number of sentences in the text, the number of words, the number of syllables in the words, and their ratios in the given text.

The dynamics and structure of each language are unique and different. Readability studies for Turkish texts have been developed since the 1990s. The most commonly used Readability Scales for Turkish texts are the Atesman (10) and Bezirci-Yilmaz (11) Readability Scales. Atesman defined readability as the ease or difficulty of a text to understand and comprehend the content of the text.

Package inserts are the most detailed texts that provide sufficient information to the patients regarding the drugs. Patients may increase or decrease the recommended dose by the physician or terminate the treatment due to misunderstanding the information on the package inserts. Incorrect or insufficient understanding of the drugs might lead to significant mortality and morbidity rates for serious diseases such as hypertension. Kasar et al. (14) examined antihypertensive drug use errors in elderly individuals and found that 57% of the patients had followed an incorrect drug use. It was also found that the rate of making mistakes was 7.2 times higher in those who read the drug inserts than in those who did not and 32% of those who did not read drug inserts stated that they did not read drug inserts because they could not understand the text. Solmaz et al. (15) conducted a study on the use of drugs by elderly people living at home and found that 77.7% of the elderly who did not read the package insert indicated that the reason for not reading the package inserts was the inability to understand the texts. These studies show that one of the important reasons for not reading package inserts is the difficulty of understanding of the text.

Ay et al. (16) evaluated the readability levels of eye drop drug inserts and found that the readability level of the package inserts was 46.8 based on the Atesman Readability Scale and 12.8 for the Bezirci-Yılmaz Readability Scale. The education required to be able to read drugs was an average of 13 years, i.e., undergraduate level. Another study evaluating the readability of consent forms used for advanced invasive procedures in cardiology clinics in Turkey reported that patients must have received at least 11 years of education to be able to read and understand the consent forms easily (17). Various studies examining the readability levels of other consent forms have yielded similar results (18–20). In our study, the readability level of antihypertensive package inserts was calculated as 52 according to the Atesman Readability Scale and 11.9 according to the Bezirci-Yılmaz Readability Scale. In other words, an average of 11-12 years of high school education is required to read these package inserts.

The average schooling year and the expected schooling year provide an idea about the education level of countries and regions. Yesilyurt et al. (21) conducted a study in 2016 and reported that the average schooling year in Turkey was 6.51 years, and the expected schooling year was 11.03. In other words, the readability level of antihypertensive package inserts was above the average schooling year in Turkey. This level must be considered when determining the texts that address different members of the society.

CONCLUSION

It was determined in the present study that an average of 11-12 years of high school education is required for antihypertensive package inserts to be readable. Considering that the average year of schooling in Turkey is 6.51 years, this level is found to be at high level. It would be more appropriate if the readability levels of the package inserts were suitable for 6 years of education. In this respect, we recommend that medication errors will decrease and treatment compliance will increase by making the package inserts easier to read and comprehend. Further, more comprehensive studies must be conducted with more comprehensive scales covering the patients' cognitive functions and vision problems.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was conducted according to the decision of the Afyonkarahisar Health Sciences University Clinical Researches Ethics Committee (Date: 05.08.2022, Decision No: 2022/400).

Informed Consent: There were no patients in our study.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper and that they have approved the final version.

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