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Analysis of the Readability of Package Inserts for Attention Deficit Hyperactivity Disorder Medications Used in Turkey

Türkiye'de Kullanılan Dikkat Eksikliği Hiperaktivite Bozukluğu İlaçlarının Prospektüslerinin Okunabilirlik Düzeyi

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ABSTRACT

Aim: The readability level of a written text is directly related to how well the text is understood.There are precise formulas that may be used to test readability objectively. The purpose of this research was to evaluate the readability of the ADHD medication package inserts that are presently in use in Turkey.
Methods: 23 medication package inserts for ADHD in total were categorized based on their types. The Turkish Medicines and Medical Devices Agency (https://www.titck.gov.tr/kubkt) provided the most updated package leaflets for the medications in these categories. The Ateşman and Bezirci-Yılmaz readability formulae, which are relevant to Turkish texts, were used to assess package inserts. The Ateşman reading score was calculated to be 72.2 (7-8th grade) on average. The Bezirci-Yılmaz formula has a reading level equivalent to grades 7-8, which corresponds to the primary school level. Based on the 2022 TUIK data in Turkey, it was found that the reading level was suitable for the average education level, except for the SNRI group (high school level).
Conclusion: Given the aforementioned information, we maintain the viewpoint that pharmaceutical package inserts for psychiatric medications ought to ideally contain content written at the level of a primary school (7-8th grade).

Keywords: drug package insert, readability, education level, ADHD

ÖZ

Amaç: Yazılı bir metnin okunabilirlik düzeyi, metnin ne kadar iyi anlaşıldığıyla doğrudan ilişkilidir. Okunabilirliği objektif olarak test etmek için kullanılabilecek kesin formüller vardır. Bu araştırmanın amacı, Türkiye'de halen kullanılmakta olan DEHB ilaç prospektüslerinin okunabilirliğini değerlendirmektir.
Yöntem: Toplam 23 DEHB ilaç prospektüsü türlerine göre kategorize edilmiştir. Türkiye İlaç ve Tıbbi Cihaz Kurumu (https://www.titck.gov.tr/kubkt) websitesinden bu kategorilerdeki ilaçlar için en güncel prospektüsler sağlanmıştır. Türkçe metinlerle için uygulanabilir olan Ateşman ve Bezirci-Yılmaz okunabilirlik formülleri prospektüsleri değerlendirmek için kullanılmıştır. Ateşman okuma puanı ortalama 72,2 (7-8. sınıf) olarak hesaplanmıştır. Benzer şekilde Bezirci-Yılmaz formülü ile de, ilkokul seviyesine karşılık gelen 7-8. sınıflara eşdeğer bir okuma seviyesi tespit edilmiştir. Türkiye 2022 TÜİK verilerine dayanarak, DEHB ilaçlarının prospektüslerinin okunabilirlik düzeyinin, SNRI grubu (lise seviyesi) hariç ortalama eğitim seviyesine uygun olduğu görülmüştür.
Sonuç: Yukarıda belirtilen bilgiler ışığında, psikiyatrik ilaçların ilaç prospektüslerinin ideal olarak ilkokul (7-8. sınıf) düzeyinde yazılmış içerik içermesi gerektiği görüşünü savunuyoruz.

Anahtar Kelimeler: ilaç prospektüsü, okunabilirlik, eğitim düzeyi, DEHB

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Introduction

Readability refers to the degree of simplicity and comprehension a text provides with its writing style. It subsequently establishes a correlation between this metric and the text's level of difficulty to read [1]. An objective method for assessing the readability of a text involves the utilization of a set of mathematical formulas that establish correlations among the word count, syllable count, and sentence length [2], [3]. In recent years, several academic studies have been carried out to evaluate the readability of pharmaceutical package leaflets, patient information forms, and health information websites. These resources are crucial for patients to get accurate information [4].

A patient information leaflet is a technical document included with every drug box and provides written information about the medication. The manufacturer provides patient information leaflets (PILs) that follow a standard structure and provide the same information for each medicine. Their primary goal is educating patients about their drug, including its administration, precautions, and adverse effects. PIL information should be objective, supported by evidence, and written in a style that is easy to read and comprehend for laypeople [5].

Attention-Deficit Hyperactivity Disorder (ADHD) is the most common neurodevelopmental disorder in children, with a worldwide incidence of 5.29% and a prevalence of 12.4% in Turkey [6]. The social cost associated with ADHD symptoms and functional impairment emphasizes the significance of regular monitoring in communities. Monitoring ADHD diagnosis, medical treatment receipt, comorbidities, and mortality is critical for timely policymaking in the healthcare system [7]. Adults and children may also suffer the negative impacts of untreated ADHD, If left untreated, ADHD has poorer long-term outcomes [8]. ADHD may result in difficulties in terms of efficiency, social connections, and other psychological health issues. Untreated adult ADHD may also result in complications such as anxiety, sadness, and drug misuse. Notwithstanding the abundance of research, parents and patients have anxieties about the use of ADHD medication. They may be hesitant because they feel some treatments could affect a child's growth. Or they fear a child or adult might get dependent on medication or might need it forever. If parents or patients read a package leaflet without seeking advice from a doctor, they may independently alter the dosage of the medication or discontinue its use. That is why, in the psychiatry field, giving information about the drug's effects and side effects is vital to the content of psychoeducational interventions directed at the patient and their family. Psychotic disorders, now considered neurodevelopmental disorders, are treated with drugs at every stage, but non-compliance with drug therapy is common in these patients, so the physician's duty does not end with drug selection. Previous research indicates that antipsychotic medication noncompliance in schizophrenia and other psychotic diseases ranges from 11% to 80% [9]. The rates of noncompliance with stimulant therapy also range from 20% to 65%, according to studies [10]. As the use of these drugs grows, it is important to make sure that information about them and any bad effects they might cause is easily understandable so that patients are safe and public health is improved. Hence, it is essential that package leaflets be written using uncomplicated and comprehensible language. In the future, they may have the potential to be used as a component of psychoeducation, an essential element of non-pharmacological interventions in the mental health domain. When we look at the studies that have been done on the effectiveness of the medicine package inserts, we find that they are not serving as the main information source for users, not just in our country but also internationally. The purpose of this research was to assess the readability of ADHD medicine package leaflets presently in use in Turkey, as well as to estimate the suitable average age and educational level.

Methods

The author prepared a list of all currently available ADHD medications from the Turkish Drug Guide website [11]. The medications were classified into five groups based on their active ingredients: psychostimulant (methylphenidate), selective noradrenaline reuptake inhibitors (SNRIs- atomoxetine), serotonin-norepinephrine reuptake inhibitors (SSNRIs-venlafaxine),

centrally acting antihypertensive drugs (clonidine, guanfacine), and others (imipramine, bupropion, and modafinil). The Turkish Medicines and Medical Devices Agency (https://www.titck.gov.tr/kubkt) provided the most updated package leaflets for the medications in these categories. By copying, the medicine package insert texts were uploaded to the "https://www.webfx.com/tools/readable/" readability calculation engine. Factors including syllable count, word count, and sentence structure influence the formulae used to objectively quantify readability, which is widely recognized in the scientific community [5]. In 1948, Flesch created the first readability formula that was widely acknowledged in literature [12]. The SPSS version 27 software was used to import the results of these computations Bezirci-Yılmaz and Ateşman's formulae were used to obtain the readability values [2,3].

Ateşman Readability Formula: Readability score =198.825 – 40.175 x word length (total syllables / total words) – 2.610 x sentence length (total words/ total sentences). A readability score ranging from zero to one hundred marks is produced by the above-mentioned formula. Text legibility is classified as "very difficult" (worth 1–29 points), "difficult" (30–49 points), "moderately difficult" (50–69 points), "easy" (70–89 points), or "very easy" (90–100 points) in the evaluation of scores. Alternatively stated, in contrast to the Bezirci-Yılmaz formula, readability improves as the score increases. The points earned may also be used to establish the educational level at which the content is appropriate (Table 1)

The Bezirci–Yılmaz readability formula: Readability score=√OKS x ((H3 x0.84) + (H4x1.5) + (H5x3.5) + (H6x26.25)). This formula, which is based on the number of words in the sentences and the number of syllables in the words, establishes the readability level of the written text in accordance with the Turkish educational system. Higher scores in this formula indicate more complexity in readability (Table 1)

Statistical Analysis

The results of the data obtained in the study were calculated as the mean and standard deviation for continuous variables. Percentage results were calculated for categorical data. The Shapiro-Wilk test was used to determine whether the data were normally distributed. The difference between multiple groups for a continuous variable was examined by One-way ANOVA in the presence of normal distribution, otherwise by the Kruskal Wallis test. Bonferroni correction was made for significance in post-hoc analysis. p-value <0.05 was considered significant. All statistical analysis was performed with SPSS version 27.

Table 1. The level of education that is equivalent to the number of points calculated using the Atesman and Bezirci-Yilmaz readability formula.

ATEŞMAN		Bezirci-Yilmaz	
Score	**Education Level**	**Grade**	**Education Level**
9-100	Primary school 4th grade and below	1-8	Primary school
80-89	5th - 6th grade	9-12	Middle school (High school)
70-79	7th - 8th grade	12-16	Further education
60-69	9th - 10th grade	16+	Academic level education
50-59	11th - 12th grade		
40-49	13th - 15th grade		
30-39	Undergraduate level		
<29	Postrgraduate level		

Results

The research was done using a sample of 23 medicines that are currently used in Turkey for the treatment of ADHD. Out of them, 5 (21.7%) medications were categorized as psychostimulants, 7 (30.4%) were categorized as SNRIs, 3 (13%) were categorized as SSNRIs, 3 (13%) were categorized as centrally acting antihypertensives, and the remaining 5 (21.7%) were grouped under other medications (Table 2). Methylphenidate was in the group of psychostimulants, venlafaxine was in the group of SNRIs, atomoxetine was in the group of SSNRIs, and clonidine and guanfacine were in the group of centrally acting antihypertensives. Imipramine, bupropion and modafinil are classified in the other group.

Based on the assessment conducted by Bezirci

and Yılmaz, it was observed that the reading level of medication inserts belonging to the psychostimulant, SSNRI, and centrally acting antihypertensive groups was equivalent to that of elementary school level.

Table 2. Classification of ADHD medications

		N	%
Pharmaceutical Group	Psychostimulants	5	21,7
	SNRIs	7	30,4
	SSNRIs	3	13,0
	Centrally Acting Antihypertensives	3	13,0
	Other	5	21,7

42.9% of the medication leaflets in the SNRI group had a reading level equivalent to that of elementary school, whereas 57.1% had a readability level equivalent to that of high school.

Within the other group, 40% of the prospectuses were categorized as being at the elementary school level, while the remaining 60% were classified as being at the high school level.

The medication leaflets included in the research did not have a reading level that was at the undergraduate or academic level (Figure 1).

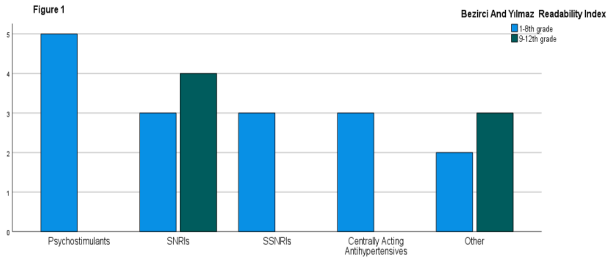

Figure 1. Readability Level of ADHD Medications According to Bezirci-Yılmaz Readability İndex

Based on the Ateşman readability index, the readability of all psychostimulants, SSNRIs, and centrally acting antihypertensive drugs was classified as 7-8th grade. The Ateşman reading score was calculated to be 72.2 on average. Out of the SNRI medication group, the readability of 57.1% of drugs fell into the category of 7-8th grade level, while 42.9% (3) fell into the category of 9-10th grade level. Within the other group, the readability of 40% of the drugs was classified into the category of 7-8th grade level, while 60% were classified as 9-10th grade (Figure 2).

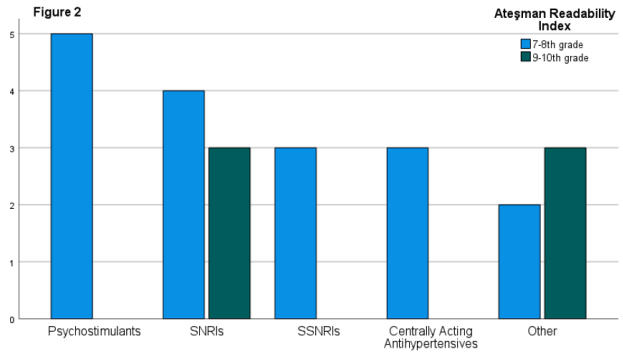

Figure 2. Readability Level of ADHD Medications According to Ateşman Readability İndex

The results of the Ateşman readability formula, the total number of words, and the total number of characters in the prospectuses are given in Table 3. When the drug was compared between groups, no significant difference was detected between the groups for the Ateşman readability index (f (4,18) = 0.771, p = 0.558). When compared in terms of word numbers, a significant difference was found between the groups (H(4) = 10.471, p = 0.033). By using the Bonferroni correction to compare each pair of groups, it was clear that the SNRI group had significantly higher words than the centrally acting antihypertensive group (p = 0.036). Although the comparison between groups revealed a significant difference in terms of the number of characters [H (4) = 9.557, p = 0.049], no significant difference was detected in pairwise comparisons (Table 3).

Discussion

When practicing their art, it is not enough for physicians to simply keep up with the most up-to-date medical information. Precisely informing patients about their medication treatments is a cornerstone deontological principle in medicine that governs patient rights and the effective administration of the treatment process. A medication package insert is a leaflet that comes with a pharmaceutical and gives instructions on how the drug should be taken and what adverse effects patients may suffer [13]. One of the most critical things that affect a patient's ability to adhere to treatment is their level of understanding of the prescription package information [14]. This is maybe more significant in mental health than in other medical specialties. In mental health illnesses, inadequate treatment compliance

Table 3. Comparison of Statistical Data of ADHD Medications' Prospectuses

		Mean ± SD	F /X2	p	Pairwise Comparisons (Adj. Sig.)d
Ateshman Readability Index	1. Psychostimulant	73,86 ±2,87			
	Ateshman	72,47 ±5,39			
	Readability	71,40 ±,529			
	Index	73,53 ±1,02			
	5. Other	69,98 ±3,85	0,771	0,558	
Word Count[c]	1. Psychostimulant	3128,80 ±512,35			
	2 SNRI	5218,71 ±1860,50			1-2(NS), 1-3(NS), 1-4(NS),
	3. SSNRI	3502,33 ±67,84			1-5(NS), 2-3(NS), 2-5(NS),
	4 Centrally Acting Antihypertensive	2051,67 ±371,08			2-4 **(p=0,036)**,
	5. Other	2694,80 ±1095,80	10,471	**0,033**	3-4(NS), 3-5(NS), 4-5(NS)
Character Count[c]	1. Psychostimulant	23981,60 ±3566,85			
	2. SNRI	41213,43 ±15981,27			1-2(NS), 1-3(NS), 1-4(NS),
	3. SSNRI	27330,67 ±533,03			1-5(NS), 2-3(NS),
	4. Centrally Acting Antihypertensive	15990 ±2817,22			2-4(NS), 2-5(NS),
	Character Countc	21517,00 ±8955,30	9,557	**0,049**	3-4(NS), 3-5(NS), 4-5(NS)

c Kruskal-Wallis Test, d Significance values have been adjusted by the Bonferroni correction for multiple tests, NS: Non significant

may impede the patient's capacity to assess reality, which adversely impacts the course of treatment. Despite the crucial role pharmaceutical drug package inserts play in providing health information, there is a scarcity of study on their readability. As far as we know, there has been no research conducted on the readability levels of ADHD medicine package inserts using the Turkish readability method. Our investigation determined that the package inserts of ADHD medicines were written at a basic level (7-8th grade) based on two Turkish readability formulae (Ateşman and Hüseyin-Bezirci). However, in the SNRI group, approximately half of the drug packages were found to have high school-level readability.

In 2011 Haw et al. examined the package inserts of antidepressant medications in the United Kingdom. Approximately 15%, or 5.1 million adults in the United Kingdom, are known to possess the level of literacy expected of children aged 11 or younger [15]. The research assessed the readability, and function of medication package inserts in enhancing patients' understanding and competence in drug use. While the readability ratings of the medicine package inserts were not very low, it was determined that they were inadequate for addressing patients' inquiries about drug use [16]. In another study from 2011, after reading an antidepressant leaflet, participants demonstrated varying levels of comprehension. 45 of the 52 participants held a high school diploma, while seven had completed less than a high school education. It was revealed that only forty percent of the attendees comprehended the material that might be considered significant, and most of them needed help to understand the directions and cautions about serious medical side effects [17]. The other article inspected the drug box inserts of the most commonly used drugs in Iran in 2015, as reported by the Social Security Organization. A

considerable proportion of the medications were identified as having inadequate readability levels, rendering them unsuitable for individuals lacking expertise in reading [18].

In a recent research revealed in Turkey in 2023, it was discovered that the package inserts of antidepressant medications were written at a reading level suitable for students in the 7th and 8th grades, as determined by two Turkish readability formulae [4]. Another Turkish study, carried out in 2021 by Ay and Duranoğlu, assessed the readability of eighty leaflets containing eye drop packages. The study determined that the average level of readability equated to thirteen years of education, or university-level knowledge. Upon examining the mean level of education in Turkey, it becomes evident that it is exceptionally high [19]. An investigation was carried out in Qatar to assess the legibility and understanding of patient information brochures about antidiabetic medications. According to the results, the materials were legible to a minimum of eleventh-grade students, and the majority of patients were incapable of understanding them [20]. A national study evaluated a variety of consent forms obtained from forty-five anesthesia departments by employing a range of readability formulas. The legibility of consent documents obtained from education and research institutions and public hospitals was comparatively low, as indicated by the Gunning Fog index. All institutions exhibited extremely low levels of legibility, as measured by the Flesch-Kincaid index. The Ateşman index revealed that the legibility of consent documents utilized in university hospitals was exceptionally low, while it was also low in other institutions [21].

Jilka S. et al.'s research from 2021 investigated the readability of a smartphone app intended for mental health, with a particular emphasis on depression. The program's readability was found to be in line with the FDA's (Food and Drug Administration) recommended reading level for eighth graders. Nevertheless, as the aforementioned survey also pointed out, the National Adult Literacy Research discovered that more than 25% of American adults struggle to read or understand written material that is beyond the fifth-grade level.

People with lesser levels of education showed a greater frequency of mental problems, according to a 2015 research done in Iran using a population-based methodology and a sample size of 36,000 people [22]. According to the findings of a review study that was carried out in 2007, which was based on earlier research carried out in the United States, fifty percent of hospitalized patients with mental illnesses were identified as being functionally illiterate. The authors advocated using both oral and written information to enhance adherence in patients with depression. They also emphasized the need to present written information in a clear and readily comprehensible manner [23].

The findings of a 2018 national study revealed that the mean educational attainment of the entire populace was 4.8 years for females and 7.1 years for males[24]. According to the information of the Turkish Statistical Institute (TUIK), the average education period in Turkey was 9.2 years in 2022. While the average duration of education received by the population aged 25 and over was 7.3 years in 2011, it increased by 26% to 9.2 years in 2022. The average duration of education for 2022 was 8.5 years for women and 10.0 years for men [25]. According to the “2023 Education at a Glance” report of the Organisation for Economic Co-Operation and Development (OECD), the rate of young people who cannot graduate from high school is higher in Turkey (33%) than the OECD average (14%). While 14.7% of young adults aged 18–24 across OECD countries are in education, employment, or not receiving education, it has been reported that this rate is higher (33.5%) in Turkey [26]. In light of these facts, information on pharmaceutical package inserts for psychiatric drugs, such as ADHD medications, should ideally be written at a primary school (7-8th grade) level. This would significantly improve comprehension and adherence to medical treatment for mental disorders, particularly in our country.

Conclusion

In conclusion, we find that understanding drug interactions with other medications taken simultaneously, as well as how they should be used, work, and cause adverse effects, is essential. It may improve adherence to therapy, which will aid in mental health rehabilitation. Additionally, it would lessen the possibility of legal issues arising

from patient and family misinterpretations of mental health practitioners. It could lessen some repeated admissions of patients. Despite the problem of patient package leaflets being difficult to read is widespread in many countries, some methods may be used to enhance their readability. Public health thus requires the creation and implementation of programs for the syntactic and semantic simplification of these documents.

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