Research Article / Araştırma Makalesi

Evaluation of the Readability of Antidepressant Drug Package Inserts Commonly Used in Psychiatry

Psikiyatride Yaygın Olarak Kullanılan Antidepresan İlaç Prospektüslerinin Okunabilirliğinin Değerlendirilmesi

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Abstract: The understanding of a written text is directly related to the readability level of that text. Readability can be measured objectively using specific formulas. In this study, we aimed to determine the readability level of the drug package inserts of antidepressant drugs. A total of 51 drug package inserts were grouped according to antidepressant types. Title and drug license information was removed from the texts for standardization. These were evaluated using the Ateşman, Bezirci–Yılmaz and Çetinkaya–Uzun readability formulas, applicable to Turkish texts. The average Ateşman readability score was determined as 71.4. Accordingly, it was seen that the drug package inserts require a grade 7-8 of education for readability. The readability level of the Bezirci-Yılmaz formula was, similarly, of grade 7-8 (primary education) level. The Çetinkaya-Uzun readability score was calculated as 45.4 and an 8-9th grade level was determined. It was ascertained that the drug package inserts were readable at the secondary education (7th-9th grade) level on average. Considering the average education level in Turkey, it was established that the readability level was therefore high. We believe that writing the drug package inserts based on the average education level will increase readability and therefore intelligibility.
Keywords: Apopitozis, Antidepressant drugs; Drug package insert; Readability; Education level

Özet: Yazılı bir metnin anlaşılabilmesi o metnin okunabilirlik düzeyi ile doğrudan ilişkilidir. Okunabilirlik ise bazı formüller kullanılarak objektif biçimde ölçülebilmektedir. Bu çalışmada antidepresan ilaçların prospektüslerinin okunabilirlik düzeyini tespit etmeyi amaçladık. Toplam 51 prospektüs antidepresan çeşitlerine göre gruplandırıldı. Standardizasyon için başlık ve ilaç lisans bilgileri metinlerden çıkarıldı. Türkçe metinler için uygulanabilir olan Ateşman, Bezirci–Yılmaz ve Çetinkaya-Uzun okunabilirlik formülleriyle değerlendirildi. Ortalama Ateşman okunabilirlik puanı 71,4 olarak tespit edilmiştir. Buna göre prospektüslerin okunabilirlik için 7-8 sınıf eğitim düzeyi gerektirdiği görülmüştür. Aynı şekilde Bezirci–Yılmaz okunabilirlik düzeyinde de 7-8. sınıf (ilköğretim) seviyesi olduğu tespit edilmiştir. Çetinkaya-Uzun okunabilirlik puanı 45,4 hesaplanmış ve 8-9.sınıf seviyesi tespit edilmiştir. Prospektüslerin ortalama olarak ortaöğretim (7-9. sınıf) seviyesinde okunabilir olduğu tespit edildi. Türkiye'deki ortalama eğitim düzeyi dikkate alındığında okunabilirlik seviyesinin yüksek olduğu görülmektedir. Prospektüslerin ortalama eğitim düzeyi baz alınarak yazılmasının okunabilirliği ve dolayısıyla anlaşılabilirliği artıracağını düşünmekteyiz.
Anahtar Kelimeler: Antidepresan ilaç; Prospektus; Okunabilirlik; Eğitim seviyesi

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1. Introduction

Readability is a concept that measures how easy it is to understand and comprehend a text based on how it is written, and then links this information to how hard it is to read the text. In recent years, several studies in the literature have examined the readability of scientific articles (1). Nowadays the degree of readability of a document can be determined by using formulas that have been developed to this end, and these tools provide precise and impartial appraisals to assess the intelligibility and coherence of a given written document (2).

Antidepressants are a group of drugs that are often used in psychiatry and their indications are progressively expanding. Many psychiatric disorders, including depression, obsessive-compulsive disorder, panic disorder, generalized anxiety disorder, post-traumatic stress disorder and social phobia, are treated with this type of medication (3). As the utilization of these pharmaceutical agents progressively broadens, it is imperative to guarantee that the dissemination of related information, as well as possible adverse reactions associated with their utilization, is conveniently understandable to ensure patient safety and the promotion of public health. Antidepressant medications are marketed by prescription but are also accessible over the counter in several countries. Users who wish to learn about the use and potential adverse effects of these medications may read the package inserts, however some patients may stop using these medications or not use them in the dose and manner recommended by their physician. For this reason, drug package inserts must be provided and should be easy to read and understand. Upon analyzing the research conducted on the efficacy of drug package inserts, it becomes apparent that they are not fulfilling their intended role as the primary source of information for users, not just within our nation, but also across the globe (4).

In this study, it was aimed to measure the readability level of the package inserts of antidepressant drugs that are frequently prescribed today.

2. Materials and methods

Ethical approval of 2023/01-23 was obtained by the Ethics Committee of Clinical Research at Kütahya University of Health Sciences.

The list of all active antidepressants available in pharmacies was compiled by the author from the current webpage of the Turkish Drug Guide (5). The current medications were classified into three groups, based on their active ingredients: selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and others. The drug package inserts texts were transferred to the readability calculation engine at "https://www.webfx.com/tools/read-able/" by means of copying. The syllable, word and sentence counts, as well as the number of words with four or more syllables in the drug package inserts texts, were duly calculated. The results obtained from these calculations were transferred to the Microsoft Excel program. The readability values were calculated using the formulas derived by Ateşman and Çetinkaya-Uzun (2, 6, 7).

2.1. The 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) and a readability score of 0–100 is obtained. As the score increases, the readability of the text increases (2) (Table 1).

2.2. The Bezirci–Yılmaz readability formula: It is the Turkish version of the readability formulas (6). It determines the readability level of the written text according to the Turkish education system, in a formulation based on the number of words in the sentences and the number of syllables in the words (Table 1). Readability score=√OKS x ((H3 x 0.84) + (H4x1.5) + (H5x3.5) + (H6x26.25))

2.3. The Çetinkaya-Uzun readability formula: The formula was developed in 2010.Readability Score = 118.823 – 25.987 x the average word length is calculated by –0.971x average sentence length. Points were level 0-34 (disabled reading - 10,11 and 12th grade), 35-50

(educational reading - 8th and 9th grade) and >51 (independent reading - 5 and 7th grade) (7) (Table 1).

2.4. Statistical analysis: The SPSS® 20 software was used for data analysis. Frequency and percentage values were used to represent categorical data, whereas the mean and standard deviation were used to represent numerical data. For normality distribution, the Kolmogorov Smirnov and Shapiro Wilk tests and histograms were used, and none of the results were consistent with the normal distribution. In the Kruskal Wallis categorical data comparisons, the Ki-square and the Fisher Exact tests were employed to compare numerical data between independent groups. The statistical analyses used in the research were conducted with a bidirectional significance limit of 5% and a confidence level of 95%.

Table 1. Ateşman and Bezirci–Yılmaz readability index scores and the corresponding education level.

Ateşman		**Bezirci–Yılmaz**		**Çetinkaya-Uzun**		
Score	**Education level**	**Grade**	**Education level**	**Score**	**Readability Level**	**Education Level**
90–10	Primary school 4th grade and below	1-8	Primary education	51 +	Independent Reading	5th, 6th and 7th grade
80–89	5th - 6th grade					
70–79	7th - 8th grade			35-50	Instructional Reading	8th and 9th grade
60–69	9th - 10th grade	9-12	Secondary and high school			
50–59	11th - 12th grade			0-34	Frustration Level	10th, 11th and 12th grade
40–49	13th - 15th grade	12-16	Licence education			
30–39	Undergraduate level	16+	Academic level education			
≤29	Postgraduate level and above					

3. Results

The research started with 74 medication packets. It was confirmed that 23 of them (31.08%) were not being actively used on the market, therefore the investigation was ultimately completed using 51 medication packets. Of these, 27 (52.9%) medicines were SSRIs, 11 (21.5%) were SNRIs, and the remaining 13 (25.6%) were TCAs and other antidepressants.

Page Count, Sentence Count, Word Count, Syllable Count, Average Sentence Length and Average Word Length data of the drug package inserts according to the groups, are presented in Table 2. The average Ateşman readability score was determined as 71.4. Accordingly, it was determined that the drug package inserts require a grade 7 or 8 of education for readability. Likewise, the readability level of Bezirci-Yılmaz is also 7-8. It was determined that there is a grade (primary education) level. Çetinkaya-Uzun's readability score was calculated as 45.4 and a 8-9th grade level was determined. No statistically significant difference was found between the groups in terms of readability status (Table 3). According to this data, the findings obtained with the three readability formulas were found to be compatible with each other (Table 4).

Table 2. Grammar statistical data of drug package inserts of antidepressant drugs.

Parameters	Groups	n	Mean	SD	Median	Minimum	Maximum
Page Count	SSRI	27	11.3	2.0	11	8	15
	SNRI	11	11.1	3.8	9	7	19
	TCA and Other	13	8.6	1.7	8	7	11
Sentence Count	SSRI	27	585.1	107.5	576	269	789
	SNRI	11	594.3	297.2	539	296	1210
	TCA and Other	13	472.9	141.3	453	293	730
Word Count	SSRI	27	3167.9	623.2	3208	2197	4446
	SNRI	11	3157.7	1361.8	2943	1724	5741
	TCA and Other	13	2340.6	666.6	2217	1608	3274
Syllable Count	SSRI	27	8790.3	1506.3	8704	6350	12400
	SNRI	11	8902.2	4011.1	8254	4748	16837
	TCA and Other	13	6718.4	1982.2	6478	4561	9663
Average Sentence Length	SSRI	27	5.4	0.7	5.60	4.30	8.20
	SNRI	11	5.4	0.7	5.50	4.30	6.50
	TCA and Other	13	5.0	0.5	5.00	4.10	5.90
Average Word Length	SSRI	27	2.81	0.0535	2.80	2.72	2.97
	SNRI	11	2.83	0.0804	2.80	2.76	3.01
	TCA and Other	13	2.85	0.0855	2.85	2.72	3.09

SSRI: Selective Serotonin Reuptake Inhibitor, SNRI: Serotonin-Norepinephrine Reuptake Inhibitor, TCA: Tricyclic antidepressant

Table 3. The average readability scores of the drug package inserts of antidepressant drugs

		SSRI (n=27)	SNRI (n=11)	TCA and Others (n=13)	Total (n=51)	p value
Ateşman readability index		71,6±3,3	70,9±2,7	71,3±3,5	71,4±3,2	,790*
Çetinkaya-Uzun Readability Index		45,7±5,6	45,4±1,5	43,9±1,6	45,4±4,2	,078*
Bezirci–Yılmaz readability index	7 – 8 grade	23(85,2%)	8(72,7%)	9(69,2%)	40(78,4%)	
	9 – 10 grade	3(11,1%)	3(27,3%)	4(30,8%)	10(19,7%)	,439**
	11 – 12 grade	1(3,7%)	0(0,0%)	0(0,0%)	1(1,9%)	

*Data are given as mean±SD or n (%). *Kruskal Wallis test, ** Chi Square test (Fisher's exact test)*

Table 4. Correlation of readability indexes of drug package inserts of antidepressant drugs

	Ateşman readability index	Çetinkaya-Uzun Readability Index	Bezirci–Yılmaz readability index
Ateşman readability index	1		
Çetinkaya-Uzun Readability Index	0,557** ,000	1	
Bezirci–Yılmaz readability index	-0,715** ,000	-0,610** ,000	1

***Correlation is significant at the 0.01 level (2-tailed).*

4. Discussion

A drug package insert is a paper that accompanies a medicine and provides information on how the drug should be administered and what side effects patients may experience (8). Reading the package insert of drugs is one of the important factors affecting knowledge and behavior in drug use (9). It is known that reading the package insert of drugs and understanding the information given about them are associated with health literacy. Understanding the drug package insert is one of the most important factors affecting adherence to treatment (10). Pharmaceutical drug package inserts are

important tools for accessing health information, yet the number of studies performed with the readability of drug package inserts is limited in the literature. To the best of our knowledge, there exists no study of the readability levels of the drug package inserts of antidepressant drugs with the Turkish readability formula. In our study, the package inserts of antidepressant drugs were found at the primary level (7-8th grade) according to two Turkish readability formulas and at a secondary level (8-9th grade) according to a formula.

Antidepressant medications are used for several purposes, over a wide variety of age groups, and at numerous dosage levels. Fibromyalgia, neuropathic pain, migraine, irritable bowel syndrome, etc., are also recommended as adjuvant treatments in many psychosomatic diseases, even though depressive disorders and anxiety disorders are the primary indicators (11-14). It is known that they are utilized in a large patient population other than the exclusive mental patient group, when their usage with comorbid disorders is also taken into account. In light of this circumstance, it is crucial to assess the reading level of all age groups, beginning with children. Poor socioeconomic status and poor education levels are related to a rise in psychiatric illnesses (15). Drug package inserts with lower reading levels will aid in greater public education in this regard.

In a study conducted in 2011, Haw et al. analysed the level of patient information in the package leaflets of antidepressant drugs in the United Kingdom. The study evaluated the content, design, readability level and the role of drug package inserts in improving patients, knowledge and skills related to drug use. Although the readability scores of the drug package inserts were not dire, it was concluded that the drug package inserts were insufficient to answer patients' questions about the use of the drug or to help them make decisions by emphasising other factors affecting readability (16). In 2015, a systematic review of the literature on the readability of drug package inserts was published, in which 22 studies published between 2008 and 2013 were analysed. This review, which analysed texts written in English, Portuguese, Italian, French and Spanish, generally emphasised the need for better readability of drug leaflets to improve patient understanding and safety. It also emphasises that better methods and standards should be developed to improve the readability of drug package inserts. It states that the content and design of drug package inserts should be appropriate for the target audience and support problem-solving skills related to drug use (17).

A study conducted in Iran in 2015, utilizing a population-based approach with a sample size of 36,000 individuals, revealed that individuals with lower levels of education exhibited a higher prevalence of mental disorders (18). According to different research, a heightened level of education serves as a safeguard against the onset of anxiety and depression (19). Recent findings regarding the correlation between educational level and psychiatric patients are lacking. However, a systematic review conducted in 2007, based on previous studies conducted in the United States, reported that 50% of hospitalized psychiatric patients were functionally illiterate (20).

In a recent article about the readability of eyedrop drug package inserts, it was stated that the drug package inserts could be understood with an average undergraduate education (21). Another recent study of over-the-counter (OTC) drug package inserts in China, the overall text-reading level of the drug package inserts was found to be equivalent to the median reading level for 12th graders (9.5 to 12) (8). Informed consent forms for intravenous and intramuscular injection were evaluated in terms of readability; according to the Ateşman readability formula of all these forms, it was found to be of moderate difficulty (9th-12th grade) and at the 7th-8th grade, according to the Bezirci-Yılmaz readability formula. It was stated that the readability of these texts was quite low (22).

In a study conducted in Qatar, the readability and comprehensibility of patient information brochures for antidiabetic medications were

examined. The findings indicated that the readability level of the materials was at least at an 11th-grade level and that most patients were unable to comprehend them (23). The other article examining the drug package inserts in Iran, a significant portion of the medications were found to possess low readability levels and were deemed unsuitable for non-expert readers (24).

In recent studies on the readability and intelligibility of various health-related materials, it has been revealed that there are incompatibilities between the readability of these materials and the reading skills of the target audience (25, 26). It is seen that the technical language used mostly in these materials makes many health-related materials difficult (27).

In a 2018 study conducted in our country, the median education level of the whole population was determined to be 4.8 years for women and 7.1 years for men (28). Considering these facts, the drug package insert information of antidepressant drugs, at the 5-6th grade level in our country, may be more likely to increase readability.

Drug package inserts should also be evaluated in terms of layout, writing style, appearance and attraction features (4). In this study, drug package inserts were evaluated only in terms of their readability and not using these features and this is the principal limitation of our study.

5. Conclusion

We conclude that it is crucial to have information about how drugs should be used, their mechanism of action, their side effects, as well as the interaction of other drugs used concurrently. It is critical to improve reading habits of drug package inserts and to provide education on what needs to be considered when reading these documents. During this process of educating and consulting, the level of health literacy of individuals may need to be taken into consideration. It is recommended that drug boxes and drug package inserts should be written using fonts which individuals can easily see and read, using words they can understand.

REFERENCES

1. Goldbort R.,Readable writing by scientists and researchers. *Journal of Environmental health*, 2001;63: 40-40.
2. Ateşman E., Türkçede okunabilirliğin ölçülmesi. Dil Dergisi, 1997; 58:71-74.
3. Sheffler ZM, Patel P, Abdijadid S (Edited by).Antidepressants: *StatPearls Publishing, Treasure Island* (FL), 2022
4. Özkan N.F., Ulutaş BH., Üniversite öğrencilerinin prospektüs kullanma bilinci ve davranışlarının araştırılması. *Selçuk Üniversitesi Fen Fakültesi Fen Dergisi*, 2018; 44:51-62.
5. Rehberi Tİ. Erişim yeri: https://www.ilacrehberi.com/ilac-fiyatlari/ 2023. Erişim tarihi 20.02.2023
6. Bezirci B., Yilmaz A.E.,Metinlerin okunabilirliğinin ölçülmesi üzerine bir yazilim kütüphanesi ve Türkçe için yeni bir okunabilirlik ölçütü. *Dokuz Eylül Üniversitesi Mühendislik Fakültesi Fen ve Mühendislik Dergisi*, 2010;12:49-62.
7. Çetinkaya, G., Uzun, L. Türkçe Ders Kitaplarındaki Metinlerin Okunabilirlik Özellikleri. Hakan Ülper (Edited by). Türkçe Ders Kitabı Çözümlemeleri. Ankara: PegemA Akademi, 2014:141-154.
8. Zheng, Y., Tang, Y., Tseng, H. C., Chang, T. H., Li, L., Chen, P., Tang Y., Lin X., Chen X., Tang K., Evaluation of quality and readability of over-the-counter medication package inserts. Research in Social and Administrative Pharmacy, 2022;18: 3560-3567
9. McDonald, H. P., Garg, A. X., Haynes, R. B., Interventions to enhance patient adherence to medication prescriptions: scientific review. *Jama*, 2002;288:2868-2879.
10. MacLaughlin, E. J., Raehl, C. L., Treadway, A. K., Sterling, T. L., Zoller, D. P., Bond, C. A. Assessing medication adherence in the elderly: which tools to use in clinical practice?. *Drugs & aging*, 2005;22, 231-255.
11. Mascarenhas RO, Souza MB, Oliveira MX, Lacerda AC, Mendonça VA, Henschke N, Oliveira VC. Association of Therapies With Reduced Pain and Improved Quality of Life in Patients With Fibromyalgia: A Systematic Review and Meta-analysis. *JAMA Intern Med.* 202;181:104-112
12. Selvy M, Cuménal M, Kerckhove N, Courteix C, Busserolles J, Balayssac D. The safety of medications used to treat peripheral neuropathic pain, part 1 (antidepressants and antiepileptics): review of double-blind, placebo-controlled,

randomized clinical trials. *Expert Opin Drug Saf*. 2020;19:707-733.
13. Oh, S. J., Takakura, W., Rezaie, A., Shortcomings of trials assessing antidepressants in the management of irritable bowel syndrome: a critical review. *Journal of Clinical Medicine*, 2020: 9;2933.
14. Burch, R., Antidepressants for preventive treatment of migraine. *Current treatment options in neurology*, 2019: 21;1-12.
15. Slominski, L., Sameroff, A., Rosenblum, K., Kasser, T. I. M., Longitudinal predictors of adult socioeconomic attainment: The roles of socioeconomic status, academic competence, and mental health. *Development and Psychopathology*, 2011:23; 315-324.
16. Haw, C., Stubbs, J., Patient information leaflets for antidepressants: are patients getting the information they need?. *Journal of Affective Disorders*, 2011:128;165-170.
17. Pires, C., Vigário, M., Cavaco, A., Legibilidade das bulas dos medicamentos: revisão sistemática. Revista de Saúde Pública, (2015). 49.
18. Noorbala, A. A., Faghihzadeh, S., Kamali, K., Yazdi, S. A. B., Hajebi, A., Mousavi, M. T., Nouri, B. Mental health survey of the Iranian adult population in 2015. *Archives of Iranian medicine*, (2017). 20(3), 0-0.
19. Bjelland, I., Krokstad, S., Mykletun, A., Dahl, A. A., Tell, G. S., Tambs, K., Does a higher educational level protect against anxiety and depression? The HUNT study. *Social science & medicine*, (2008). 66(6), 1334-1345.
20. Desplenter, F. A., Simoens, S., Laekeman, G. The impact of informing psychiatric patients about their medication: a systematic review. *Pharmacy World and Science*, (2006). 28, 329-341
21. Ay, İ. E., Duranoğlu, Y., Göz damlası prospektüslerinin okunabilirlik düzeyinin değerlendirilmesi. *Anatolian Clinic the Journal of Medical Sciences*, (2022). 27(1), 55-59.
22. Emre, E. B. E. M., Tutar, M. S., YILDIZ, M., CANITEZ, A., Özlem, K. A. R. A., Kozanhan, B. İntravenöz ve intramüsküler enjeksiyon bilgilendirilmiş onam formlarının okunabilirlik açısından değerlendirilmesi. *Anatolian Clinic the Journal of Medical Sciences*, (2019). 24(2), 132-136.
23. Munsour, E. E., Awaisu, A., Hassali, M. A. A., Darwish, S., & Abdoun, E.,Readability and comprehensibility of patient information leaflets for antidiabetic medications in Qatar. *Journal of Pharmacy Technology*, (2017). 33(4), 128-136.
24. Zarea Gavgani, V., Mirzadeh-Qasabeh, S., Hanaee, J., & Hamishehkar, H., Calculating reading ease score of patient package inserts in Iran. Drug, healthcare and patient safety, (2018). 9-19.
25. Rudd, R. E., Health literacy skills of US adults. *American journal of health behavior*, 2007;31;8-18.
26. Piñero-López, M. Á., Modamio, P., Lastra, C. F., Mariño, E. L., Readability assessment of package inserts of biological medicinal products from the European medicines agency website. *Drug safety*, 2014;37:543-554.
27. Schwartzberg, J. G., Cowett, A., VanGeest, J., & Wolf, M. S. Communication techniques for patients with low health literacy: a survey of physicians, nurses, and pharmacists. *American journal of health behavior*, 2007;31;96-104.
28. Eryurt, M. A., Arslan, H., Güneş, K., Bani, B., 2018 Türkiye Nüfus ve Sağlık Araştırması İleri Analiz Çalışması. Hacettepe Üniversitesi Nüfus Etütleri Enstitüsü, Ankara, T.C. Cumhurbaşkanlığı Strateji ve Bütçe Başkanlığı ve TÜBİTAK. 2021.

Ethics

Ethics Committee Approval: The study was approved by Kütahya University of Health Sciences Noninterventional Clinical Research Ethical Committee (Decision no: 2023/01.23, Date: 11.01.2023

Informed Consent: The authors declared that it was not considered necessary to get consent from the patients because the study was a retrospective data analysis

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