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ARAŞTIRMA MAKALESİ / RESEARCH ARTICLE

Evaluation of the Readability of Package Inserts for Hormone Replacement Therapy, Combined Oral Contraceptives, and Progestin-Only Pills: A Cross-Sectional Analytical Study

Hormon Replasman Tedavisi, Kombine Oral Kontraseptifler ve Yalnızca Progestin İçeren Hapların Prospektüslerinin Okunabilirliğinin Değerlendirilmesi: Analitik Araştırma: Kesitsel Çalışma

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ÖZET

Amaç: Yazılı bir metnin anlaşılması, okunabilirliği ile doğrudan ilişkilidir. Okunabilirliği objektif bir şekilde ölçmek için belirli formüller vardır. İlaç prospektüslerinin okunabilirliği de halk sağlığı açısından önemlidir. Özellikle reçetesiz satılan ve doğrudan temin edilebilen ilaçlarda bu prospektüslerin anlaşılabilirliği ve okunabilirliği daha da önem arz etmektedir. Bu çalışmada hormon replasman tedavisi (HRT), kombine oral kontraseptiflerin (COCP) ve sadece progestin içeren hapların (POP) prospektüslerinin okunabilirlik düzeyinin belirlenmesi amaçlanmıştır.

Materyal ve Metod: Türkiye İlaç ve Tıbbi Cihaz Kurumu' nun resmi web sitesinden eczanelerde satılan ve kadınların kullanabildiği tüm reçetesiz ve reçeteli hormon preparatlarının listesini oluşturdu. Türkiye' de reçeteli veye reçetesiz olarak satılan hormon preparatları içeriklerine göre HRT, COCP ve POP olarak üçe yarıldı. İlaç prospektüs metinleri okunabilirlik hesaplama motoruna aktarıldı ve metinlerindeki hece, kelime ve cümle sayıları hesaplandı. Türkçe metinler için geçerli olan Ateşman, Bezirci-Yılmaz ve Çetinkaya-Uzun okunabilirlik formülleri, bu metinleri değerlendirmek için kullanıldı. Araştırma, %5 çift yönlü anlamlılık sınırı ve %95 güven düzeyi ile gerçekleştirilmiştir.

Bulgular: Üç ilaç grubu için Ateşman okunabilirlik endeksinin ortalama değerleri 70,5 ile 71,3 arasında oldukça benzerdir (p=0.690). Çetinkaya-Uzun okunabilirlik endeksinin ortalama değerleri, 49,9 ile 50,7 arasında oldukça benzerdir (p = 0,627). Bezirci-Yılmaz, üç ilaç grubu için okunabilirlik endeksinin iki kategoriye ayrıldığını göstermektedir: 7-8 sınıf ve 9-10 sınıf. Her bir ilaç grubuna ait prospektüslerin çoğunluğunun 7-8 sınıf kategorisine girdiğini, prospektüslerin okunmasının ve anlaşılmasının oldukça kolay olduğunu göstermektedir. Üç farklı ilaç grubu için Bezirci-Yılmaz okunabilirlik endeksi arasında anlamlı bir fark yoktur (p=0.534).

Sonuç: Türkiye'deki ortalama eğitim seviyesi göz önüne alındığında bu preparatraların prospektüslerinin okunabilirlik seviyesi yüksektir. İlaç prospektüslerinin ortalama eğitim seviyesine göre yazılması okunabilirliğini ve dolayısıyla anlaşılabilirliğini artıracaktır.

Anahtar Kelimeler: Hormon replasman tedavisi, kombine oral kontraseptifler, okunabilirlik, prospektüs, sadece progestin içeren haplar

ABSTRACT

Aim: The comprehension of a written text is directly related to its readability. There are specific formulas to objectively measure readability. The readability of package leaflets is also important for public health. This study aimed to determine the readability level of the package inserts of hormone replacement therapy (HRT), combined oral contraceptives (COCP), and progestin-only pills (POP).

Material and Methods: The official website of the Turkish Medicines and Medical Devices Agency created a list of all over-the-counter and prescription hormone preparations that are sold in pharmacies and can be used by women. Hormone preparations sold with or without a prescription in Turkey are divided into three groups according to their content: HRT, COCP, and POP. Ateşman, Bezirci-Yılmaz, and Çetinkaya-Uzun readability formulas, which are valid for Turkish texts, were used to evaluate these texts. The research was conducted with a two-sided 5% significance level and a 95% confidence level.

Results: The mean values of the Ateşman readability index for the three drug groups were quite similar, between 70.5 and 71.3 (p = 0.690). The mean values of the Çetinkaya-Uzun readability index were quite similar, between 49.9 and 50.7 (p = 0.627). Bezirci-Yılmaz shows that the readability index for the three drug groups is divided into two categories: 7-8 grade and 9-10 grade. The majority of the package inserts for each drug group fall into the 7-8 grade category, indicating that the package inserts are quite easy to read and understand. There is no significant difference between the Bezirci-Yılmaz readability index for three different drug groups (p = 0.534).

Conclusion: Considering the average level of education in Turkey, the readability level of the package inserts for these preparations is high. Adjusting the language and structure of package inserts to align with the average education level will increase the readability and, therefore, the comprehensibility. Future studies could incorporate factors such as visual presentation and user feedback to enhance the comprehensibility of package inserts.

Keywords: Hormone replacement therapy, combined oral contraceptives, readability, package insert, progestin-only pills

INTRODUCTION

Hormone replacement therapy (HRT) is generally recommended for climacteric, peri-, and postmenopausal symptoms (1). Combined oral contraceptives (COCs) are used as a means of preventing pregnancy but can also be used in many cases of menstrual irregularities (2). Additionally, progestin-only pills (POP) are used especially in women who may have difficulty with COCs and in breastfeeding women for birth control purposes (3).

Package inserts are documents that provide information about the use, dosage, side effects, safety, and risks of a drug. It aims to help patients and healthcare professionals make informed decisions about the safe and appropriate use of medicines. It is important that patients understand the information in the package insert so that they can use the medicine safely and effectively. However, it is important to consider the readability of the package inserts for these medications so that patients can understand the package insert information and make informed decisions about their own health. However, studies have shown that package inserts are often difficult to read and understand for the general public, especially those with low literacy levels or limited health knowledge (4, 5).

Readability measures the ease with which a text can be grasped and understood, and then relates this rating to the level of difficulty in understanding the text. Readability level is one of the main criteria used to evaluate whether the package inserts are understood by patients (6). It is therefore important to evaluate the readability of drug package inserts and examine whether there are any differences between different drug groups.

The primary aim of the current research was to measure the readability level of the package inserts of hormone-containing drugs that are widely used by women in Turkey and can be used without a doctor's supervision. In addition, the study aimed to determine the specific age groups for which the text content of the prospectuses in question is most appropriate and the level of education at which readability is possible.

MATERIALS AND METHODS

The study was approved by the relevant ethics committee of Necmettin Erbakan University (No: 2024/5089). These data were obtained from the official website of the Turkish Medicines and Medical Devices Agency (7). The package inserts published on this website have been approved by the relevant institution during the registration and marketing of drugs. Therefore, this study can be considered a reliable and valid source of data to evaluate the readability of drug package inserts. The list of all prescription or over-the-counter hormone preparations actively sold in pharmacies and available to women was obtained by the authors from the official website of the Turkish Medicines and Medical Devices Agency (7). Existing drugs were divided into three groups according to their content: HRT, COCP and POP.

Drug package insert texts were copied and transferred to the readability calculation engine at "https://www.webfx.com/tools/readable". The number of syllables, words and sentences in the drug package insert texts were calculated. Readability values were calculated using formulas developed by Ateşman, Bezirci-Yılmaz and Çetinkaya-Uzun.

Ateşman readability formula: The readability score of the text is calculated according to the number of syllables in the words and the number of words in the sentences. Texts with a high number of syllables and a low number of sentences are more difficult to read. As the score increases, the readability of the text also increases. Readability score: 198.825–40.175 x word length (total syllables/total words)–2.610 x sentence length (total words/total sentences). Readability scores of texts vary between 0 and 100. 100 points represent the easiest-to-read texts (Table 1) (8).

Bezirci-Yılmaz readability formula: It is a formula used to measure the readability of texts written in Turkish. It gives a score calculated based on the sentence length and word length of the text. Readability score $=\sqrt{OKS}$ x ((H3 x 0.84) + (H4x1.5) + (H5x3.5) + (H6x26.25) (Table 1) (9).

Çetinkaya-Uzun readability formula: It is a method developed in 2010. It gives a score calculated based on the average word length and average sentence length of the text. The higher the score, the easier the text is to read. Readability Score = 118.823 – 25.987 x average word length, calculated by 0.971 x average sentence length (Table 1) (10).

Statistical analysis

SPSS® 26 software was used for data analysis. Frequency and percentage values were used to represent categorical data, while mean and standard deviation were used to represent numerical data. Kolmogorov Smirnov and Shapiro Wilk tests and histograms were used for normality distribution. One way ANOVA was used to compare numerical data, and Chi-square and Fisher Exact tests were used to compare categorical data. Pearson correlation test was used to correlate the readability indexes. The statistical analyses used in the research were carried out with a 5% two-sided significance limit and a 95% confidence level.

RESULTS

Readability scores are numerical measures of how easy or difficult it is to read and understand a text. The table compares the readability scores of Ateşman, Bezirci-Yılmaz, and Çetinkaya-Uzun, which are commonly used in Turkish. Table 1 shows the comparison of three different readability scores and their corresponding education levels. Ateşman readability score varies between 10 and 90, with higher scores indicating easier texts. The score is based on the average number of syllables per word and the average number of words per sentence. The table also shows the level of education corresponding to each score range, from primary school to postgraduate level and above.

Bezirci-Yılmaz readability score varies between 1 and 16, with lower scores indicating easier texts. The score is based on the number of sentences, words, and syllables in a text. The table also shows the grade level corresponding to each score range, from 4th grade and below to academic-level education.

Table 1. Comparison of Ateşman, Bezirci-Yılmaz, and Çetinkaya-Uzun readability scores and related education levels

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					
60–69	9th - 10th grade		Secondary and	35-50	Instructional Reading	8th and 9th grade
50–59	11th - 12th grade	9-12	high school	0-34	Frustration Level	10th, 11th and 12th grade
40–49	13th - 15th grade	12-16	Licence education			
30–39	Undergraduate level		Academic level			
≤29	Postgraduate level and above	> 16	education			

Table 2. Descriptive statistics of the characteristics of the package inserts of hormone replacement therapy, combined oral contraceptive pill, and progesterone-only drugs.

Parameters	Type	Mean	SD	Median	Minimum	Maximum
Page count	HRT	14.0	6.0	13	5	29
	COCP	17.7	5.6	18	8	31
	POP	11.3	5.1	10.00	6	25
Word count	HRT	3771.3	2264.7	3361	1196	9978
	COCP	5104.6	1471.8	5469	2073	7266
	POP	2724.7	1354.9	2192.50	946	6418
Character count	HRT	30279.7	18033.1	27349	9463	79286
	COCP	40776.7	11684.8	43109	17206	59271
	POP	22162.6	11197.7	18015.50	7697	53755
Difficult word count	HRT	141.7	103.2	140	42	440
	COCP	141.5	52.2	150	59	237
	POP	89.6	42.5	96.50	24	183
Short word count	HRT	694.3	449.2	682	202	1963
	COCP	906.0	276.9	949	356	1463
	POP	463.2	222.6	363.00	152	924
Percentage of short words	HRT	18.2	1.5	18	16	22
	COCP	17.5	0.8	18	16	19
	POP	17.1	1.4	17.00	14	20
Characters without spaces	HRT	26251.6	15587.0	23716	8199	68635
	COCP	35513.3	10318.2	37525	14826	51631
	POP	19272.8	9717.8	15687.5	6706	46804
Sentence count	HRT	728.2	402.7	632	254	1772
	COCP	932.1	284.5	976	347	1446
	POP	549.9	260.0	470.5	246	1254
Paragraph count	HRT	524.0	277.8	497	176	1253
	COCP	675.7	200.2	725	262	924
	POP	390.7	173.9	336.0	168	850
Average word count	HRT	2.8	0.05	2.85	2.68	3.01
	COCP	2.8	0.08	2.85	2.68	2.97
	POP	2.8	0.19	2.87	1.97	2.97
Average sentence count	HRT	5.1	0.66	5.00	3.70	6.20
	COCP	5.5	0.66	5.50	4.10	7.50
	POP	4.9	0.54	5.00	3.80	6.10

HRT: Hormone replacement therapy, COCP: Combined oral contraceptive pill, POP: progesterone-only pill.

Table 3. Comparison of the readability indices according to the groups of drugs.

Readability index		HRT (n=13)	COCP (n=27)	POP (n=24)	Total (n=64)	p value
Ateşman		71.3 ± 3.02	71.0 ± 3.03	70.5 ± 2.51	70.9 ± 2.81	0.690*
Çetinkaya-Uzun		49.9 ± 2.95	50.7 ± 2.47	50.0 ± 5.08	50.3 ± 3.70	0.627*
Bezirci – Yılmaz	7-8 grade	9 (69.2%)	14 (51.9%)	15 (62.5%)	38 (59.4%)	0.534**
	9-10 grade	4 (30.8%)	13 (48.1%)	9 (37.5%)	26 (40.6%)	

* One way ANOVA, ** Chi-Square test. HRT: Hormone replacement therapy, COCP: Combined oral contraceptive pill, POP: progesterone-only pill.

Table 4. Correlation of readability indices of package inserts of drugs.

		Ateşman readability index	Çetinkaya-Uzun readability index	Bezirci–Yılmaz readability index
Ateşman readability index	r	1		
	p			
Çetinkaya-Uzun readability index	r	0.375	1	
	p	0.002		
Bezirci–Yılmaz readability index	r	-0.763	-0.211	1
	p	0.0001	0.094	

p: p values; r: Pearson correlation coefficient.

Çetinkaya-Uzun readability score varies between 0 and 51, with higher scores indicating easier texts. The score is based on the percentage of difficult words and short words in a text. The table shows the education level corresponding to each score range from 5th grade to 12th grade.

Table 2 shows descriptive data on HRT, COCP, and POP package inserts. The table compares each medication type's mean, standard deviation, median, minimum, and maximum text features (pages, words, characters, etc.). COCP package inserts are the longest and most thorough of the three medication categories, with the highest mean values for pages, words, characters, phrases, and paragraphs. POP package inserts are the smallest and most brief of the three drug categories, with the lowest average pages, words, characters, sentences, and paragraphs. HRT package inserts utilize more complicated vocabulary and shorter words than the other two classes of drugs, with the highest mean values for difficult terms and proportion of short words. Compared to the other two drugs, COCP package inserts employ the fewest difficult terms and short words. POP package inserts had the greatest mean average word count, showing they utilize more words than the other two drugs. HRT box inserts feature the fewest sentences compared to the other two categories of drugs. COCP package inserts had the largest mean number of sentences, indicating longer sentences than the other two drugs.

Table 3 compares drug group readability indices. Ateşman finds that the three drug groups had similar readability index values of 70.5 to 71.3. A One-way ANOVA test demonstrates that the three drug groups' Ateşman reading index mean values are not significantly different (p = 0.690). The typical Çetinkaya-Uzun readability index values are comparable, ranging from 49.9 to 50.7. A One-way ANOVA test indicates no significant change in the mean Çetinkaya-Uzun reading index values across the three medication groups (p = 0.627). Bezirci-Yılmaz identifies two readability index categories for three medication groups: 7-8 and 9-10. The data demonstrates that most medication group leaflets are class 7-8, indicating that they are easy to read and understand. The Chi-Square test indicates no significant difference in Bezirci-Yılmaz readability index categories across the three medication groups (p = 0.534). The table illustrates that the three medication classes have similar readability and complexity indices.

Table 4 shows the correlation of the readability indices of drug package inserts. The Ateşman readability index has a positive and moderate correlation with the Çetinkaya-Uzun readability index (r = 0.375, p = 0.002) and a negative and strong correlation with the Bezirci-Yılmaz readability index (r = -0.763, p < 0.0001). shows. It shows that the Çetinkaya-Uzun readability index has a negative and weak correlation with the Bezirci-Yılmaz readability index (r = -0.211, p = 0.094).

DISCUSSION

Readability is a concept that measures how easy it is to understand and comprehend a text based on how it is written. This metric correlates with how difficult the text is to read based on how it is written. Many recent studies in the literature have evaluated the readability of scientific articles (11). Nowadays, developed formulae can be used to assess the intelligibility and consistency of a written document. These tools can be used to accurately and objectively assess the intelligibility and consistency of documents (8). The extent to which a patient's behavior (such as taking medication, following a diet, changing habits, or attending clinics) matches the recommendations of medical or healthcare professionals is known as compliance (12). Understanding the drug package insert is one of the most

important factors affecting compliance with treatment (13). To achieve optimal therapeutic results, drug information must be of high quality and be understandable and readable. Studies in the literature on the readability of drug package inserts, which facilitate access to health information, are limited. To our knowledge, there is no study examining the readability levels of the package inserts of HRT, COCP, and POP, which are frequently used in gynecology practice, using a Turkish formula. Our study shows that the majority of the package inserts for each drug group fall into the 7-8 class category, which shows that the package inserts are quite easy to read and understand.

Health literacy is "the capacity of individuals to obtain, process, and understand basic health information and services necessary to make appropriate health decisions."(14). Health literacy is crucial to action on treatment choices, medication use, patient support, and health information (15). Patients are expected to have access to appropriate drug information in an era dominated by information and communication technology. Package inserts, in addition to the verbal and/or pictorial information given to patients when taking medications, are crucial to ensuring they use medications safely and effectively and comply with instructions.

Various mathematical techniques can be used to determine the readability and suitability of a text according to its educational level. Flesch developed the first readability formula in the first half of the 1900s (16). Readability formulas, informed consent, behavior therapy manuals, and psychological tests are increasingly used to evaluate the field's written resources (17). Although readability tests do not give a definitive idea of the understandability of the text, they do give an idea of the level of understandability of the text (18).

HRT, COCP and POPs can be purchased without a prescription in our country and many countries. People who want to learn about the use and possible side effects of these drugs can read the package inserts. As the use of these agents becomes increasingly common, relevant information and an understanding of the potential side effects associated with their use are needed to improve patient safety and public health. However, some patients may discontinue or discontinue use of these medications in the dosage and manner recommended by their doctor. Therefore, drug package inserts should be easy to read and understand.

In our study, we found that COCP package inserts were the longest and most detailed documents of the three drug types and had the highest average number of pages, words, characters, sentences, and paragraphs. We have observed that POP package inserts are the shortest and most concise documents. We found that HRT leaflets used a shorter and more complex vocabulary than the other two types of medicines. Compared to the other two types of medications, COCP package inserts had the lowest mean values for the number of difficult words and the percentage of short words. This shows that they use longer vocabularies and more complex vocabularies. We observed that longer words were used in POP package inserts than in the other two types of drugs. We found that HRT

package inserts used shorter sentences, on average, compared to the other two types of medicines. We found that COCP package inserts used longer sentences, on average, compared to the other two types of medications. When we compared the drug groups according to their readability indices, we found that most of the package inserts for each drug group fell into the 7–8 class category; there was no significant difference in readability indices between the three drug groups, and they had the same readability and complexity levels. This shows that no matter how different the age of use and package inserts of these agents are, they do not make a difference in terms of readability. Although the package insert of HRT, which is used especially in older age groups, seems to be more complex, the use of shorter sentences does not make its readability different from other agents. While the average years of education of the population aged 25 and over in our country was 7.3 years in 2011, it increased by 26% to 9.2 years in 2022. In 2022, the years of education for women was 8.5 years and for men was 10.0 years (19). The fact that most of the package inserts for each drug group are in the 7th to 8th grade category and that the years of education for women in our country is 8.5 years explains why these texts have similar readability levels.

In a study evaluating the readability of antidepressant drug package inserts, it was determined that the average Ateşman readability score was 71.4 and that 7th or 8th grade education was required for readability. Bezirci-Yılmaz's readability level was found to be 7-8. Çetinkaya-Uzun's readability score is 45.4, and an 8–9 grade level was determined. There was no statistically significant difference between different antidepressant agents in terms of readability (5). In another study, they investigated the level of patient information in the package inserts of antidepressant drugs. In the study, the content, design, and readability of drug package inserts and their role in improving patients' knowledge and skills regarding drug use were examined. Although the readability scores of drug package inserts are not very low, other factors affecting readability are emphasized, and it is concluded that package inserts are inadequate for answering patients' questions or making decisions regarding drug use (20).

In Ay et al.'s study on the readability of eye drop drug package inserts, it was observed that drug leaflets could be read with an average undergraduate degree (21). Informed consent forms for intravenous and intramuscular injection were of medium difficulty (grades 9–12) according to the Ateşman readability formula and grades 7-8 according to the Bezirci-Yılmaz readability formula. It was determined that it was at grade level. These texts were found to be difficult to read (22). A study conducted in Qatar investigated how readable and understandable the package inserts of antidiabetic drugs were. These findings showed that the materials were readable at at least a fourteenth grade level and that most patients were unable to understand them. They concluded that because only English versions were evaluated and US-based comprehensibility scores were used for some formulas, they may not be applicable to the diverse population in Qatar (23).

In the study of Dağdelen et al., the readability of the

consent forms used in gynecology and obstetrics clinics was investigated. Using the Bezirci-Yılmaz and Ateşman readability formula, it was found that longer training periods were necessary for the readability of the consent forms in obstetrics and gynecology (24).

There are several limitations to this research. Since the number of drugs included in the study was limited, it may not be correct to generalize the research results for all drugs. The font and point size used in the analyzed texts were not taken into account. Points about visual organization and the absence of patient feedback are other limitations of the study. Additionally, how well patients were able to understand these package inserts has not been examined.

CONCLUSION

In recent years, the number of studies on the readability of consent forms, health-related websites, and drug package inserts has increased. There is no research comparing the Turkish readability formulas of HRT, COCP, and POP package inserts, which are prescribed by doctors in gynecology and obstetrics practice or can be purchased without a prescription from pharmacies. Considering that the average education level of women in Turkey is 8.5 years according to 2022 data, it seems that the prospectuses are suitable in terms of readability as they fall into the 7-8 grade category. However, this study only reviewed the readability of drug package inserts. No layout, text style, appearance, or attention-grabbing elements have been used. These factors should also be taken into account. New research should examine readers' characteristics such as age, mental status, and visual acuity, as well as their educational level. Improving the readability and accessibility of package inserts is essential for enhancing patient compliance and safety, particularly in populations with lower health literacy.

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