

Evaluation intelligibility of urology consent forms

Üroloji onam formlarının anlaşılabilirliğinin değerlendirilmesi

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ÖZET

Amaç: Bu çalışmada üroloji kliniğinde invaziv işlemler için kullanılan onam formlarının hastalar tarafından anlaşılabilirliğini araştırdık. Kliniğimizde kullanılan onam formlarını hangi yaş ve eğitim gruplarının kavrayabileceği değerlendirildi.

Gereç ve Yöntemler: Bu araştırmada Ateşman ve Bezirci-Yılmaz tarafından Türkçe için önerilen iki anlaşılabilirlik formülü kullanılmıştır. Çalışmada 69 ayrı onam formu değerlendirildi.

Bulgular: Onam formları Ateşman anlaşılabilirlik indeksi kullanılarak değerlendirildikten sonra çalışmada ortalama 62,02 puan elde edilmiştir. Bu değer, 9 ve 10. sınıf eğitim düzeyine sahip bir kişinin metni anlayabileceğini gösterir. Bezirci-Yılmaz indeksi aynı formlar incelendiğinde ortalama 11,13 puan vermiştir. Bu değer, onam formlarının 10 ve 11. sınıf eğitim düzeyine sahip olanlar tarafından anlaşılabilirliğini göstermektedir.

Sonuç: Çalışmamızda hastalara operasyon öncesi verilen bilgilendirilmiş onam formlarının hastalar tarafından anlaşılmasında yetersiz kaldığı tespit edilmiştir. Literatürde daha önce yapılan çalışmalarda da benzer bulgular elde edilmiştir. Bilgilendirilmiş onam formları oluşturulurken her ülkenin kendi sağlık okuryazarlığı ve eğitim düzeyi dikkate alınmalıdır.

Anahtar Kelimeler: üroloji onam formları, anlaşılabilirlik, üroloji

ABSTRACT

Objective: In this study, we investigated the understanding of the consent forms used for invasive procedures in the urology clinic by the patients. It was evaluated which age and education groups could comprehend the consent forms used in our clinic.

Material and Methods: In this investigation, we employed two intelligibility formulas proposed by Ateşman and Bezirci-Yılmaz for Turkish. In the study, 69 separate consent forms were evaluated.

Results: An average of 62.02 points was obtained in the study after evaluating the consent forms using the Ateşman intelligibility index. This value indicates that a person with a 9 and 10th education level will be able to comprehend the text. The Bezirci-Yılmaz index yielded an average of 11.13 points when the same forms were analyzed. This value indicates that consent forms can be understood by those with a 10 and 11th grade education grade.

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This study was approved by the Antalya Training and Research Hospital Clinical Researches Ethic Committee (Approval Number: 17-14. Date: 04/11/2021). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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Conclusion: In our study, it was found that the informed consent forms given to the patients before the operation were insufficient to be understood by the patients. Similar findings were obtained in previous studies in the literature. Each country's own health literacy and education level should be taken into account when creating informed consent forms.

Keywords: urology consent forms, intelligibility, urology

INTRODUCTION

The term "intelligibility" refers to the reader's ability to comprehend a text. Today, mathematically developed scales can be used to determine a text's intelligibility. This has been accomplished using a variety of approaches (1). Gunning-Fog looked at the length of words, the number of words in a phrase, and the number of sentences in a text to see which age group it could be understood by in 1952 (2). In addition to indicating the age at which intelligibility occurs, the Flesch-Kincaid value also showed the level of intelligibility based on the reader's educational grade (3).

While evaluating consent forms, criteria such as the number of sentences, the number of words in the sentences, the number of syllables in the words, and the use of technical terms were used. In this method, more than 40 criteria for intelligibility were identified (4). The Turkish Urology Association created consent forms for clinical usage in urology and published them on their website. The goal of this study is to see how well the consent forms published by the Turkish Urology Association are understood by people of various ages and educational levels.

MATERIAL AND METHODS

In our country (Turkey), many different consent forms are used in different clinics. Consent forms include general consents and customized consents specific to the invasive procedure to be performed. The 69 consent forms recommended and widely preferred in clinical use by the Turkish Urology Association were analyzed in this study.

Each form was saved in the Notepad software from Microsoft (Microsoft Corporation, Redmond, WA). The clarity of the texts was evaluated according to the criteria prepared by Ateşman and Bezirci-Yılmaz for Turkish consent forms. The software prepared by Bezirci-Yılmaz was used for the evaluation.

Ateşman readability formula:

It is a formula based on word and sentence length and was developed by adapting the Flesch reading ease formula to Turkish. According to this formula, it is understood that a text is easy to read as its readability score approaches 100 and difficult to read as it approaches 0.

Readability score = $198,825 - 40.175 \times \text{word length (total syllables / total words)} - 2,610 \times \text{sentence length (total words / total sentences)}$.

Bezirci-Yılmaz readability formula:

It is a formula developed in 2010 based on the statistical characteristics of Turkish, using the number of words in the sentences in the texts, word length and different formulas. The readability level calculated by multiplying the syllable numbers of the words with their unique numbers is formulated as follows:

OKS: Average word count

H3: 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

According to this formula, as the number of words in the sentences in the texts increases, the readability level of the texts decreases. Likewise, the increase in word length complicates the readability of words and sentences. The result obtained from this formula is a text. It reports which class level it addresses in the education system of our country.

RESULTS

Consent forms in our study were analyzed according to the Ateşman intelligibility index and an average score of 62.02 was obtained. It was seen that this result corresponded to the comprehension by the ninth and tenth grade students. In the evaluation made according to the Bezirci-Yılmaz criteria, the agreement of the texts was 11.13. This result showed that the evaluated consent forms were understandable at the tenth and eleventh grade levels. When the consents were evaluated according to Ateşman criteria, it was revealed that ten consents were intelligible at the eleventh and twelfth grade levels. While two consents were at the seventh and eighth grade levels, one consent was intelligible at the thirteenth grade level. The other forms were considered to be understandable by students in high school (grades 9, and 10). At the primary school level, no form was considered to be understandable. When evaluated according to the Bezirci-Yılmaz criteria, it was revealed that 8 consents were at primary school, 36 consents were at high school (grades 9, 10, 11, 12), 24 consents were at undergraduate level (grades 13, 14, 15), and one consent was intelligible at graduate level (Table 1 and table 2). The results were analyzed with statistical analysis and data evaluation program, and the average of the readability index was determined. Statistical Package of Social Sciences 22 (SPSS Chicago, IL, USA) program was used for analysis. Continuous variables were expressed as mean±standard deviation and median (25th percentile–75th percentile), while categorical variables were expressed as numbers and percentages. Numerical data made between more than 2 independent groups in the study One-way analysis of variance was used for comparisons.

Table 1. The relationship between the Ateşman comprehensibility index and the comprehensibility level and results

Index	Comprehensibility Level	Results
90 – 100	Can be easily understood by students in 4th grade and below	
80 – 89	Can be easily understood by students in 5th and 6th grade	
70 – 79	Can be easily understood by students in 7th and 8th grade	2
60 – 69	Can be easily understood by students in 9th and 10th grade	56
50 – 59	Can be easily understood by students in 11th and 12th grade	10
40 – 49	Can be easily understood by students in 13th or 15th grade (undergraduates)	1
30 – 39	Can be easily understood by university graduates	
≤ 29	Can be easily understood by university postgraduates	

Table 2. The relationship between the Bezirci-Yılmaz comprehensibility index and the comprehensibility level and results

Index	Education Level	Results
1–8	Primary school	8
9-12	High school	36
12-16	Undergraduate	24
16+	Postgraduate	1

DISCUSSION

Fresch developed the first substantial version of intelligibility in 1948 (5). To calculate the ease of reading according to the Fresch form, the ratio of syllables to words and words to sentences was used. Mclaughlin devised the Simple Gobbledygook (SMOG) measurement in 1969. The SMOG value is determined by counting words containing three or more letters. Syllables and sections are evaluated by using at least ten phrases taken from the first, middle and last parts of the text. The level of intelligibility related to the value is determined after applying the mathematical formulas (6).

The Automatic Readable Index (ARI) formula was developed by Simit and Senter in 1967 to standardize the clarity of documents used in the US military. The length of words in documents and the number of letters in all words are calculated. As a result, the text's intended audience is determined (7).

The Ateşman formula was created in Turkey in 1997. While the length of Turkish sentences was between nine and ten words, the length of the words was found to be 2.6 syllables. When these data are combined with Ateşman's mathematical method, it is possible to establish the educational level the text is appropriate for (8).

In 2010, Bezirci-Yılmaz proposed a new intelligibility formula for Turkish. This formula uses the total amount of words, sentences, syllables, letters, and words containing more than four syllables. According to the average number of syllables in the words in the text, a word distribution graph is made. The information gathered determines the text's intelligibility based on the reader's educational level (9).

In the study of Ebem et al. published in 2019, ninety different intravenous and intramuscular consents were evaluated according to Ateşman and Bezirci-Yılmaz formulas. The intelligibility of the intramuscular and intravenous consent forms used in this study was found to be quite low. According to Ebem et al., Ateşman's intelligibility score of 56 points corresponded to students in the eleventh and twelfth grades. The result was in agreement with the present study. Again in the study, it was found that 9.43 points correspond to the 10th and 11th grades according to the Bezirci-Yılmaz intelligibility criteria. Although this result is compatible with the present study, the level of intelligibility is lower than the Bezirci-Yılmaz index (10).

In a study conducted at a Dermatology Center in Tehran, the clarity of the forms used was investigated using the Flesch-Kincaid and Gunning-Fog indices. It was seen that the examined forms were understandable at the level of 11th grade students. The researchers regarded this as an exceedingly poor level of comprehension of the consent documents.

The American Medical Association and the National Institutes of Health conducted a research with seven different formulas, including Flesch Kincaid. According to the research, consent forms for invasive treatments were written at a level of intelligibility equivalent to a fifteenth-grade education level on average. The average education level of adults living in the United States is eighth grade. Understanding the forms used for interventional procedures is extremely difficult due to the low level of education. The American National Institutes of Health recommended that consent forms for invasive procedures be written at an appropriate level for sixth-year students.

Shuba et al. examined 113 different consent forms used for oncology patients receiving radiotherapy at 89 different clinics. It was found that the 100 forms examined were understandable at the tenth to fourteenth grade education level. The number of intelligible consent forms at the eighth and sixth grade levels was found to be four each. In the study of Shuba et al., it was revealed that patient consent forms should be written in a better understandable way (11).

It is legally and ethically obligatory for patients to understand what will be done to them before an invasive procedure and to sign an informed consent form. The individual providing consent must be properly informed and capable of consenting to the intervention. To properly inform the patient, complete information regarding why the intervention is essential, how it will be performed, the patient's advantages, potential problems, and other treatment options should be provided.

Sönmez et al. evaluated the readability of consent forms for open, endoscopic, and laparoscopic surgery in a previous urology study and found no statistically significant difference between the three groups. In their study, Sönmez et al. used criteria such as sentence length, number of words and number of syllables in words in consent forms. Patients' anxiety levels are likely to be high prior to surgery, which may influence the text's readability. In addition, the size and quality of the font used in the text are also factors that affect readability. It can be said that new informed consent forms should be prepared according to the demographic characteristics of the patient such as age, education level, gender, and whether or not she has visual impairment. In Turkey, which has an average education level of 6.51 years, consent forms should be written legibly and according to a lower education level. For a visually impaired patient, it will be much more difficult to read a consent form before an invasive procedure. These patients should be provided consent documents that are more clear and understandable. In this area, more research is required (12).

CONCLUSION

As a result, it was revealed that the comprehensibility of the consent forms used in the urology clinic of the training and research hospital, which is a tertiary hospital, was quite low. Considering that the incidence of diseases such as benign prostatic hyperplasia, prostate cancer, kidney cancer and bladder cancer, which occupy a large place in the urology clinic, increases with age, the patient group requiring interventional procedures will be above the average age of the Turkish population. The education level of elderly patients in Turkey is likely to be lower than the national average. As a result, any informed consent form used in the urology clinic should be understandable by at least primary school graduates. It was observed that the agreement of the consent forms examined in our study was low in line with the findings of similar studies. Consent forms should be prepared by considering the education level of each country. In this way, the legal liability limits of healthcare workers can be better established.

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