Assessment of patients’ knowledge level regarding the informed consent from the ethical aspect

Itir Erkan1,*, Yildiz Mayadagli2, Murat Akbaba3

Abstract: Informed consent is one of the fundamental personal rights for an individual to know and determine what will be done to his/her own body, and also for legalizing the procedure. The objective of this study is to determine the awareness level of patients about the patient rights and the written consent obtained in medical facilities before the treatment. In year 2015, the questionnaire consisting of 3 sections was conducted on 102 patients hospitalized in surgical departments of Cerrahpasa Medical Faculty Hospital of Istanbul University. The statistical analyses of this study were performed using SPSS 19.0 package program. Of the participants, 63 declared that they know what the informed consent means, 39 (38.1%) declared that they have not sufficient knowledge on this subject, while 74 (72.5%) of participants stated that they were informed about the risks and adverse effects of operation to be performed and 28 (27.4%) were not sufficiently informed. In this study, it was determined that the patients were not sufficiently informed about the informed consent, and that there still are words, meaning of which are not known by the patients. More sensitive approach of the professionals and administrators working at medical facilities to this matter would eliminate the risks from the legal and ethical aspects and also prevent the physicians from suffering from the legal sanctions.

Key Words: Informed consent, medical facilities, ethics, patient, healthcare professional.

In Article 17 of the Constitution of the Republic of Turkey, the physical integrity is taken under protection, and it is stated that, except for the medical requirements and the situations specified by the law, the physical integrity of any individual should not be violated and no individual should be exposed to scientific or medical experiments without his/her obvious consent” [1]. For this reason, since it is one of the fundamental personal rights for an individual to know and determine what will be done to his/her own body, and also for legalizing the procedure, it is required to obtain the informed consent of the patient prior to the intervention. This fundamental right and the legal obligation are the basis for obliging the medical professionals for obtaining the informed consent of these patients. The patient should give the written consent to the physician about the procedure prior to the intervention due to this fundamental right. For this written consent to be valid, the patient should be clearly and understandably informed about the types, benefits, potential risks, and the chance of success of any sort of intervention to be proposed to the patient, as well as the alternative treatment options, if any, and possible consequences of denying the intervention [2]. Even if the enough information is provided, the patient might claim that he/she was not sufficiently briefed because of the use of medical terms in consent form. For that reason, it is important to use a language, which the patient can understand, while preparing the form [3].

One of the prerequisites of obtaining a valid and appropriate consent is to achieve it after informing

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the patient about the procedure and by granting him/her enough time for evaluating them. Especially for the patients having no emergency situation and no legal or medical problem limiting his/her ability to make a decision about his/her life, it is clearly stated in Article 4 of European Status of Patient Rights that all of the information that the person needs for making an effective and sufficient assessment should be provided minimum 24 hours before the intervention. Within this time, the patient would be allowed to effectively think about his/her own future and to get the opinion of his/her relatives and/or a physician [4, 5].

The person obliged to inform is the physician, who is principally a party to the contract of mandate. Besides that, the obligation of informing may be fulfilled by another physician having knowledge about the situation. If the patient has been receiving treatment for a long time by the specialists from multiple branches because of his/her disease, each of the specialists is obliged for providing information on his/her branch. In American legal system, it has been emphasized that the obligation of obtaining the written consent belongs to the physician that is being and will treat, and that this task should not be delegated to technician, nurse, practitioner, hospital administration or consultant physician [5-7]. Prior to any kind of medical intervention to be performed in medical facilities, it is very important for the consent to be clearly understood by the patient from the possible problem in terms of legal, ethical, and administrative problems. That's to say, the informed consent should be specific to the patient and his/her disease, and it should be known that the printed consent is not valid from the legal aspect. At the end of consent form, the patient should sign the document by specifying that the written consent was granted upon receiving sufficient and understandable information.

This study aims to determine the awareness level of patients about the patient rights and the written consent obtained in medical facilities before the treatment.

MATERIALS AND METHODS

The universe of our study consists of 102 patients, who were older than 18 year-old in year 2015, hospitalized in surgical departments of Istanbul University Cerrahpasa Medical Faculty, and accepted to participate in our questionnaire study. This study was approved by the Istanbul Cerrahpasa Medical University Ethics Committee (2015/A26). The questionnaire form was divided into 3 sections; demographic information in 1st section, information about the clarification process in 2nd section, and the 3-Point (yes, no, partially) Likert scale for determining the knowledge levels of participants in 3rd section. The statistical analyses were performed by using SPSS 19.0 package software. The categorical variables are expressed in frequency and percentage. Intergroup comparisons of categorical variables were performed by using Pearson’s Chi-Square, Yates Chi-Square, and Fisher’s Exact Chi-Square. In all of the statistical analyses in this study, the level of significance was set at 0.05.

RESULTS

In this study, 51 (50%) males and 51 (50%) females (a total of 102 patients) participated. Of the participants, 45 (44.1%) were in 18-39 age group, 29 (28.4%) in 40-59 age group, and 28 (27.4%) in 60-79 age group. 11 participants (10.8%) literate, 36 (35.3%) were graduated from elementary school, 35 (34.3%) from high-school, and 20 (19.6%) from university or higher. Given the occupational statuses, it was determined that 44 participants (43.1%) were actively employed, 32 (31.3%) were unemployed, and 26 (25.5%) were retired (Table 1).

Table 1. Demographic data

<table>
<thead>
<tr>
<th>Age</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-39</td>
<td>45</td>
<td>44.1</td>
</tr>
<tr>
<td>40-59</td>
<td>29</td>
<td>28.4</td>
</tr>
<tr>
<td>60-79</td>
<td>28</td>
<td>27.4</td>
</tr>
<tr>
<td>Sex</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Female</td>
<td>51</td>
<td>50.0</td>
</tr>
<tr>
<td>Male</td>
<td>51</td>
<td>50.0</td>
</tr>
<tr>
<td>Education</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Literate</td>
<td>11</td>
<td>10.8</td>
</tr>
<tr>
<td>Elementary school</td>
<td>36</td>
<td>35.3</td>
</tr>
<tr>
<td>High school</td>
<td>35</td>
<td>34.3</td>
</tr>
<tr>
<td>University or higher</td>
<td>20</td>
<td>19.6</td>
</tr>
<tr>
<td>Occupational status</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Employed</td>
<td>44</td>
<td>43.1</td>
</tr>
<tr>
<td>Unemployed</td>
<td>32</td>
<td>31.3</td>
</tr>
<tr>
<td>Retired</td>
<td>26</td>
<td>25.5</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
<td>100</td>
</tr>
</tbody>
</table>

In our study, it was determined that almost all of the consent forms were given prior to the intervention and the patient was granted enough time for thinking. Given the verbal consents, it was determined that 78 (76.4%) of the participants received the verbal consent from supervisor physician and 18 (17.6%) from nurse, while 6 (5.9%) declared that they didn't receive any. In written consent, 74 (72.5%) declared that they received informed consent from supervisor physician and 26 (25.4%) from the nurse, while 2 patients (1.96%) stated that they didn't receive any. Although 13 participants noticed that there are information about the nurses in informed consent form, 24 participants (23.5%) declared that there isn't any and 65 participants (63.7%) stated that they didn't even know that there was such a section (Table 2).

Sixty-three of the participants declared that they knew what the informed consent form means, 39 (38.1%) declared that they have not sufficient information on this subject, while 74 (72.5%) of participants stated that
they were informed about the risks and adverse effects of operation to be performed and 28 (27.4%) were not sufficiently informed.

About the process during the briefing, 79 participants (77.3%) declared that the words, meaning of which the patients didn’t know, were used and 28 participants (27.4%) declared that they were not sufficiently satisfied from the briefing prior to operation, while 91 (89.2%) patients stated that they know the diagnosis before the operation, 5 (4.9%) had no information, and 6 (5.8%) partially knew. 45 (44.1%) patients stated that he/she has knowledge on the patient rights, 39 (38.2%) have not any, while 18 (17.6%) have partial knowledge (Table 3).

**DISCUSSION**

In medicine, the concept of informed consent has become an ethical milestone in last 60 years, and it is based on voluntariness, information sharing, compliance, and authorization [8, 9]. The consent is generally obtained in written but, in some cases, it may be verbal especially for the non-invasive and relatively non-risky interventions [10, 11]. Besides that, for the effective execution of this process, it is very important to provide the patient with sufficient information and to grant him/her enough time. In a study (2011), where they investigated the surgery patients’ knowledge levels on the informed consent, it was determined that most of the patients (70.2%) have not adequate knowledge on this subject [12]. In a study, which was carried out in year 2010 on 106 patients, it was emphasized that only 38% of the patients understood the informed consent given prior to the operation [13]. In our study, when it was asked what the informed consent means, only 39 (38%) of patients were found to have inadequate knowledge. In a study (2005), 89.9% of the patients declared that they have been told why they had to have medical operation, but 74.2% of them found this explanation to be not satisfactory [14]. In our study, 99% of the patients were told why they had to have medical operation, but 27.4% of them were not satisfied with this briefing. Given this data, we believe that this difference between the societies stems from the differences in educational status, perception, and expectations of the societies. Moreover, it can be seen that there is an improvement in recognition of the importance of informed consent among our physicians and patients.
that the physicians brief patients more, and that the requests of patients on this subject gradually increased.

In our study, when compared to male patients (47.5%), the larger portion of female patients (76.5%) stated that they know the meaning of informed consent, and this difference was found to be statistically significant (x2=5.83; p<0.05). It was interpreted in the way that, about their diseases, the female patients are not as recessive as they are in social life, and that they interest in their health more than male patients do.

When compared to employed/retired patients (54%), unemployed patients (76.3%) stated that they know the meaning of informed consent to a larger extent, and the difference was found to be statistically significant (x2= 6.51; p<0.05). It was determined that there were statistically non-significant differences between the age and educational status and informed consent (p>0.05). When these two data were examined together, it was concluded that more detailed studies should be carried out on what the informed consent really is, in addition to the relationship between educational status and unemployment.

It was determined that there was a statistically significant difference between the educational status and the refusal of treatment upon learning the operation's adverse effects such as the refusal rates were found to be higher than those of high-school and university graduates (18.2%). This finding indicates that the individuals having higher educational status consider the potential risks more reasonable, that they consider that the complications might occur as a natural consequence of intervention, and that they can better establish the cost-profit balance between the diseases and treatments.

While statistically significant difference was found between the educational status and the question “Were you told when you will return to your normal activities” (x2=14.8, p<0.043), no statistically significant difference was found between sex, age, and employment status (p>0.05). It was determined that university-graduated patients and those having higher educational status were in struggle for obtaining information, and that the patients having other educational levels were not interested in obtaining adequate level of information on the diseases. This indicates that, among the patients graduated from university and the individuals having higher educational status, the effort for integrating with the social life is higher when compared to others. Moreover, during the briefing, the patient also actively joins in the process. For this reason, because of the higher expectations of patients, who have higher educational status, from the treatment and also their consciousness levels than those of other education groups, we believe that their ability to understand what is told and also their level of awareness are high.

In performed studies, it can be seen that almost
50% of the patients responded the question “Were the words, meaning of which you didn’t know, used during the briefing” with the answer “yes/partially” [15, 16]. In our study, 44% of the patients responded with the answer “yes/partially” indicating that the words, meaning of which they didn’t know, were used. Achieving this finding that is in parallel with the literature is an indicator that the physicians used a language other than the language that the patients can understand. The physicians should show maximum effort to brief the patients by using a clear language that they can easily understand.

It is known that misinformation and disinformation are considered within the scope of malpractice. According to the Turkish Penal Law, where one would apply for determining the penal responsibilities of physicians due to their medical practices, it is required to obtain the informed consent, which is one of the three prerequisites of legality of physicians’ medical practice [17]. In a study (2006) emphasized that the process of getting the consent should be executed both verbally and in written. Moreover, they suggested that the deficiencies in the process of consent might be improved with the contributions of legal and medical experts and hospital administrators [18]. In another study, it was suggested to prepare the informed consent forms specific to the disease of patient or to the operation to be performed, to let the patient read it, to re-explain it if the patient didn’t understand, and then to get the signed consent together with the statement on it indicating that the patient understood context [19].

CONCLUSION

In summary, as it has been worldwide corroborated by the international publications, it was determined in our study that the patients are still not briefed sufficiently and the words, meaning of which the patients don’t know, are used throughout this process. In modern world, the concept of medical error has changed in scope; it has passed far beyond the assessment of physician’s ability of interpretation or direct intervention, and it has started to question if the physician appropriately utilizes the present method and techniques and if he/she is authorized for this practice [20]. While the modern medicine revolves to this process in regard to the malpractice, the facing with problems from the aspect of physicians and institutions becomes inevitable in cases of any negative development, if the patient grants the consent without exactly understanding the procedure and the potential risks. The informed consent should be extensively discussed throughout the curriculum in medical faculties, and the institutions should organize in-service trainings on this matter frequently. More sensitive approach of the professionals and administrators working at medical facilities to this matter would eliminate the risks from the legal and ethical aspects and also prevent the physicians from suffering from the legal sanctions.

Conflict of interest. The authors declare that there is no conflict of interest arising out of this manuscript.

References