SCIE DOI: 10.14744/scie.2023.50465
South. Clin. Ist. Euras. 2023;34(2):112-120

Original Article

Cross-sectional Study about Informed Consent for Patients Undergoing Hyperbaric Oxygen Treatment

Selin Gamze Sümen,[1] Esin Akgul Kalkan,[2] Özgür Özerdoğan[3]

[1]Department of Underwater and Hyperbaric Medicine, University of Health Sciences, Kartal Dr. Lütfi Kırdar City Hospital, İstanbul, Türkiye
[2]Çanakkale Onsekiz Mart University, Faculty of Medicine, Forensic Medicine Department, Çanakkale, Türkiye
[3]Çerkezköy District Health Directorate, Tekirdağ, Türkiye

Submitted: 31.01.2023
Revised: 14.05.2023
Accepted: 14.05.2023

Correspondence: Selin Gamze Sümen,
University of Health Sciences, Hamidiye International Medical Faculty,
İstanbul, Türkiye
E-mail: sgsumen@gmail.com

Keywords: Decision; hyperbaric oxygen treatment; information; informed consent; mini-mental test.

This work is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License.

ABSTRACT

Objective: In this study, we aimed to evaluate the processes of informed consent and identify factors affecting the comprehension and decision-making of the patient who undergoes hyperbaric oxygen treatment (HBOT).

Methods: This cross-sectional study group consisted of patients admitted to the Department of Underwater and Hyperbaric Medicine. Patients were verbally informed about the process and allowed to read the informed consent form before they received HBOT. Having provided the information of consent, the participants completed a questionnaire including the descriptive features, an informed consent checklist form, a Standardized Mini Mental Test (SMMT), and screening tests for decisional conflict. The results were evaluated.

Results: Fifty-six patients participated in the study. The mean age was 46.4±13.5 years and 75% of patients were men. Among the participants, 5.4% tended to feel uncomfortable with the decision they made, and 7.1% experienced decisional conflict. When the patients were asked "Who is the best person to decide about the treatment recommended for you?", 53.6% of patients responded as "The doctor." When the scales and form points used in the study were compared in terms of gender and educational level, statistically significant differences were observed between the points for SMMT (0.048) according to gender and the points for SMMT (0.001) as well as the screening test for decisional conflict (0.027) according to educational status.

Conclusion: The current research is the first study in the literature to show the crucial role of informed consent and the factors affecting comprehension as well as the decision of the patient undergoing HBOT. As a result, Underwater and Hyperbaric Medicine physicians must consider various aspects of the consent process to reduce the risk of malpractice and ensure good clinical practice.

INTRODUCTION

Hyperbaric oxygen treatment (HBOT) is a medical treatment, in which a patient inhales 100% oxygen at higher pressures than sea level. It is used in treating various health problems including decompression sickness, arterial gas embolism, carbon monoxide intoxication, delayed wound healing (diabetic and nondiabetic, etc.), and sudden hearing loss.[1] HBOT is administered in a pressurized environment, and sometimes, the patients may find the procedure difficult to understand due to the technical and medical terms used during the consent process. In addition, some side effects or complications may occur just like other medical therapies. Thus, it is crucial to provide the adequate information to the patient and maintain the patient's full compliance with the treatment to minimize complex situations with possible negative outcomes from happening. Treatment compliance can be ensured by explaining all aspects of HBOT to the patient as well as responding to all possible questions that might be arisen from the patient. This way, patients are fully informed about the details of HBOT, and valid informed consent is obtained.

The informed consent process is defined as the patient being provided with adequate information, making sure that the patient understands the procedure as well as the patient making a decision voluntarily.[2] Studies suggest that

there are several factors that affect the ability to make decisions during the process of the consent of patients. These factors include characteristics of patients such as age, literacy level, and mental state. In addition, possible side effects, complications, and uncertainties related to the prognosis of treatment may lead the patient to experience decisional conflict.[2-4]

Decisional Conflict Scale (DCS), which was developed by O'Connor in 1995, has been used to evaluate personal perception of the uncertainty, modifiable factors effecting to uncertainty, and effective decision making in their choices.[5] Furthermore, the Sure of myself; Understand information; Risk-benefit ratio; Encouragement (SURE) test version which was developed for daily clinical practice is used to determine the patient's conflict in the decision.[6,7] In addition, the Mini-Mental Score test can be performed to evaluate the mental state of the patient in clinical practice rapidly.[8] Thus, it will be possible to discuss or handle the issues that the patient has conflicts with the decision of treatment in the informed consent process.

From a legal perspective, there are many cases in the literature, in which physicians are accused of malpractice due to insufficient consent or failure to obtain written consent.[9,10] The scope and adequacy of informed consent in these legal cases are still being debated. To the best of our knowledge, there has not been any malpractice case that is particularly associated with the procedure of obtaining informed consent from a patient who underwent HBOT in underwater and hyperbaric medicine. However, due to the increase in malpractice claims and the application of HBOT, it was considered crucial to discuss the issues associated with the informed consent process in this scientific field. In fact, there has not been any research carried out about the patient's informed consent in the administration of HBOT in the literature. Therefore, we aimed to study the processes of informed consent and to identify factors affecting the comprehension and decision-making of the patient who undergoes HBOT.

MATERIALS AND METHODS

Research Type and Population

This study is a cross-sectional descriptive research. The population of the study comprised patients aged 18 years and older receiving HBOT from January to December 2016. 294 patients were administered HBOT during the research period; however, the study group consisted of 56 participants. Reasons for not participating in the study included being younger than 18 years and not volunteering to participate the survey.

Implementation of the Research

This research was conducted at the department of Underwater and Hyperbaric Medicine, at State Hospital. Before the study, written permission was obtained from the Ethical Committee (Date: September 03, 2015, Decision no: 75, 89513307/1009/494). Patients were read the HBOT Informed Consent Form by the research team with the aim of providing information to the patients regarding the disease and treatment procedure. When patients attended the clinic for their next session, the information on the form was explained to them verbally, and any questions about elements on the form that were not understood, or other questions were responded to. After the information session, patients who accepted treatment provided written/signed consent through this form. Patients were given information about the study's aim and method, and those who volunteered to participate had the questionnaires applied to obtain research data. The questionnaire comprised a descriptive form,/Standardized Mini Mental Test (SMMT), DCS, and SURE scale. Questionnaires which lasted 35–40 min were applied with face-to-face interview techniques by the physician specialized in Underwater and Hyperbaric Medicine.

Forms and Scales used in the Research

HBOT informed consent form

This form was created by the research team. It was used with the aim of providing information to people about HBOT and to receive written and signed consent before treatment. This form included general information about HBOT, the disease requiring the patient to receive HBOT, planned HBOT duration, expected success rates, expected benefits after treatment, additional treatments that may be required after HBOT, alternative treatment approaches to HBOT, and explanations of possible HBOT side effects.

Descriptive form

This form was created by the research team. This form included questions related to the patient's sociodemographic characteristics, disease status associated with HBOT (diagnosis and comorbid diseases), and attitude to be informed about illness and treatment.

HBOT informed consent checklist form

This checklist form was prepared by the research team referring to the literature.[11] It included 23 questions to assess the patient's understanding of information given through the HBOT Informed Consent Checklist Form.

SMMT

The SMMT is used to quantitatively measure cognitive level. It comprises 11 items collected under five main headings of orientation, recording memory, attention and calculation, recall, and language. Each correct response is assessed as "1" point and the point interval is 0–30. Validity and reliability studies were completed for patients with mild dementia diagnosis by Güngen et al. In this study, the ideal threshold value for mild dementia diagnosis in Turkish society was reported as 23/24.[8] SMMT points of 24–30 are defined as normal cognitive functioning, 23–20 points indicate mild cognitive disorder, and 19 points or less indicate moderate-severe cognitive function disorder.[12]

DCS

It measures the conflict experienced while making health-related decisions. It includes 16 items with 5-point Likert responses. These items comprise subscales of informed, values clarity, support, uncertainty, and effective decision-making. Items on the scale are given points as definitely agree=0, agree=1, undecided=2, disagree=3, and definitely disagree=4. Total scale points are obtained by adding the points for the 16 items, dividing the total by 16 and then multiplying by 25. According to the scoring system given, if a participant answers all the questions or the majority of them with absolute agreement, the total score is less than 0 or 1. Therefore, the total score varies between 0 and 100. Individuals with scale points ≥37.5 tend to be uncomfortable with their decision and postpone decision-making. Validity and reliability studies were completed with a thesis study of women with early-stage breast cancer.[13]

SURE

This scale was developed by O'Connor in 1995. It assesses the status of being sure about a decision made in relation to health. It comprises four 2-point Likert items. Items on the scale have points calculated as No=0 and Yes=1. The point interval for the scale is 0–4. Zero points indicate high uncertainty about the decision, whereas 4 points represents being sure of the decision. Scale points ≤3 indicates uncertainty about the decision.[14] There were no Turkish validity and reliability studies found in the period when this study was performed. As a result, the scale was translated to Turkish by the researchers and applied. At present, there is a Turkish validity and reliability study for the scale completed with pregnant participants by Yeşilçınar and Güvenç.[15]

Statistical Analysis

Data in the study were analyzed with the statistical program used the Statistical Product and Service Solutions (SPSS) (version 20.0; SPSS /IBM Inc., Chicago, IL, USA) program. Presentation of data used number, percentage, mean, standard deviation, median, minimum, and maximum values. According to the results of normal distribution fit tests, the nonparametric Mann–Whitney U test and Spearman correlation analysis were applied. Correlation coefficients from 0 to 0.24 are assessed as weak correlation, 0.25–0.49 are moderate, 0.50–0.74 are strong, and 0.75–1.0 are very strong correlation. A $p<0.05$ was considered statistically significant.

RESULTS

The study group included a total of 56 people, with a mean age of 46.4±13.5 (median: 46.0, minimum-maximum: 18–72) years and 75% were men. Among participants, 78.6% were married and 53.6% had educational level of high school and above. In the study group, thirty participants graduated from high school or above, 26 participants had the education level of lower than high school. Of the 42 men in the group, 25 had an education level high school or above, whereas five of the fourteen women had a high school education or above. The frequency of the disease requiring HBOT was shown in Table 1. The most frequently identified chronic diseases in the whole population were diabetes (32.1%), hypertension (17.9%),

Table 1. Descriptive features of the study group

Variables	n (%)
Gender	
Female	14 (25.0)
Male	42 (75.0)
Diagnosis	
Sudden idiopathic sensorineural hearing loss	17 (30.4)
Diabetic foot	12 (21.4)
Chronic wound	8 (14.3)
Osteomyelitis	5 (9.0)
Postoperative wound	4 (7.1)
Aseptic necrosis	4 (7.1)
Crush injury	4 (7.1)
Wound healing problem after radiotherapy	1 (1.8)
Postoperative spondylitis	1 (1.8)
Marital status	
Married	44 (78.6)
Single	12 (21.4)
Education	
Below high school	26 (46.4)
High school and above	30 (53.6)
Chronic disease	
Yes	30 (53.6)
No	26 (46.4)
Chronic disease*	
Diabetes	18 (32.1)
Hypertension	10 (17.9)
Peripheral artery disease	9 (16.1)
Coronary artery disease	6 (10.7)
Chronic renal failure	2 (3.6)
Other	9 (16.1)
SMMT points	
≤19	1 (1.8)
20–23	9 (16.1)
24–30	46 (82.1)
DCS points**	
<37.5	51 (91.1)
≥37.5	3 (5.4)
SURE points	
>3	52 (92.9)
≤3	4 (7.1)

n: number, %: column percentage, *: more than one response could be given to this question, each response was calculated as percentage of 56 people in the study group, **: two participants did not want to answer all or some of the questions on the decisional conflict scale, this variable was calculated as percentage of 56 people in the study group, SMMT: Standardized mini mental test, DCS: Decisional conflict scale, SURE: decision certainty scale

Table 2. Opinions of patients about information process in the study group

Variables	Yes n (%)	Partly n (%)	No n (%)
Attitude to learn information about health status	53 (94.6)	1 (1.8)	1 (1.8)
Content of information required			
Related to disease diagnosis and prognosis	50 (89.3)	1 (1.8)	3 (5.4)
Related to treatment methods	46 (82.1)	1 (1.8)	5 (8.9)
Related to supplementary treatment methods	45 (80.4)	3 (5.4)	5 (8.9)
Related to treatment outcomes	50 (89.3)	0 (0.0)	2 (3.6)
Person who can make best decisions about the recommended treatment		**n (%)**	
Doctor		30 (53.6)	
Self		21 (37.5)	
Family		4 (7.1)	

n: number; %: percentages calculated for the number of responses to the question among 56 people in the study group, a few participants did not want to answer all or some of the questions.

and peripheral artery disease (16.1%). While 1.8% of participants had moderate-severe cognitive disorder (SMMT points ≤19), 16.1% had mild cognitive disorder (SMMT points=20–23), 5.4% tended to feel uncomfortable with the decision (DCS points ≥37.5), and 7.1% experienced decisional conflict (SURE points ≤3).

Among participants, 94.6% stated they wanted to learn information related to health status, whereas 1.8% stated they wanted to receive partial information. In the study group, 89.3% wanted to receive information about disease diagnosis and prognosis, 82.1% about treatment methods, 80.4% about additional treatment methods, and 89.3% about treatment outcomes. When the patients were asked "who is the best person to decide about treatment recommended for you?," 53.6% responded as "the doctor," 37.5% said themselves, and 7.1% said their family (Table 2).

When responses of participants to questions on the informed consent checklist form are investigated, 94.6% were given information about diagnosis, all were given information about needing HBOT, 89.3% were informed about what they would encounter if they did not have HBOT treatment, all were told about treatment complications and side effects, 76.8% were informed about administration of serum, medications elevating blood sugar, or lowering blood pressure during HBOT and 83.6% were informed about whether there were other routes for treatment. Responses to other questions on the informed consent checklist form are shown in Table 3.

Mean points for the study group were 26.6±3.3 (median: 27.0, minimum-maximum: 15.0–30.0) for the SMMT, 12.6±16.2 (median: 6.3, minimum-maximum: 0.0–100.0) for the DCS, and 3.9±0.3 (median: 4.0, minimum-maximum: 3.0–4.0) for SURE. When the scales and form points used in the study were compared in terms of gender and educational level, statistically significant differences were observed between the points for SMMT (0.048) according to gender and the points for SMMT (0.001) as well as the screening test for decisional conflict (0.027) according to educational status.

Median SMMT points were determined to be high for men and for those with educational level of high school and above. All of those with educational level of high school and above had SURE points of 4 (Table 4). There were no statistically significant correlations identified between SMMT points with DCS and SURE points for participants ($p>0.05$).

DISCUSSION

As far as we know, this is the very first study in the literature to cover informed consent by patients undergoing hyperbaric oxygen therapy. The comprehension levels of patients for the information given and factors related to the patient's decision have been investigated. The most important result of this study indicated that more than half of the patients thought that their doctor could make the best decisions related to their treatment. Another notable result of the study illustrated that the variation in patient certainty about the decision-making process is associated with their level of education.

It is known that, due to the principle of respect for the patient's autonomy in terms of medical ethics, no medical intervention should be performed without receiving the patient's consent. To receive legally valid consent, the patient's capacity and understanding of the medical information provided by the physician are crucial factors. For this reason, the patient should be informed appropriately in accordance with their sociocultural level and acknowledgment of this information should be ensured.[2-4] In addition to the explanation of the beneficial effects of HBOT, the patient must be informed that it is a treatment method where they might experience some complications including barotrauma, myopia, cataracts, and pulmonary oxygen toxicity.[1] Therefore, patients must be informed about

Table 3. Responses to questions on the informed consent checklist form

Questions	Yes n (%)	Partly n (%)	No n (%)
Were you told about the diagnosis related to your disease?	53 (94.6)	3 (5.4)	0 (0.0)
Were you told the reason you should have HBOT?	56 (100.0)	0 (0.0)	0 (0.0)
Were you informed about whether or not there were other treatment routes for your disease?	46 (83.6)	3 (5.5)	6 (10.9)
Were the risks of HBOT and the life-threatening side effects explained?	56 (100.0)	0 (0.0)	0 (0.0)
Were explanations made about what would happen if you did not have HBOT?	50 (89.3)	4 (7.1)	2 (3.6)
Was the team who would perform the treatment introduced to you?	53 (94.6)	1 (1.8)	2 (3.6)
Were you told that if you did not want to, you did not have to give consent for this intervention?	54 (96.4)	1 (1.8)	1 (1.8)
Were explanations made that serum and medications that elevate blood sugar or lower blood pressure may be administered during HBOT?	43 (76.8)	5 (8.9)	8 (14.3)
Were the devices and tools you saw operating under high pressure around the HBOT explained?	54 (96.4)	2 (3.6)	0 (0.0)
Were you told where you would receive treatment and care after the end of HBOT?	51 (91.1)	4 (7.1)	1 (1.8)
Was the effect on your treatment, job, family life and other personal topics explained?	50 (90.9)	4 (7.3)	1(1.8)
Were you informed about rules and routine procedures you must abide by during HBOT?	55 (98.2)	1 (1.8)	0 (0.0)
Was there anything you did not accept on the form you signed?	9 (16.4)	1 (1.8)	45 (81.8)
According to the information the health team gave you, did you think you would benefit sufficiently from this treatment?	50 (90.9)	4 (7.3)	1 (1.8)
Were words that you did not understand used during the information session?	8 (14.6)	2 (3.6)	45 (81.8)
Were all your questions answered clearly?	54 (96.4)	2 (3.6)	0 (0.0)
Did you understand all the information and explanations given to you?	53 (94.6)	3 (5.4)	0 (0.0)
Were you satisfied with the information session before HBOT?	55 (98.2)	1 (1.8)	0 (0.0)
Do you believe that information about your health status and treatment will be confidential?	50 (89.3)	4 (7.1)	2 (3.6)
Was the interview environment comfortable during the information session?	54 (96.4)	1 (1.8)	1 (1.8)
Was the duration of the interview sufficient during the information session?	55 (98.2)	1(1.8)	0 (0.0)
Were you given adequate time to think during the decision-making process for HBOT?	54 (96.4)	2 (3.6)	0 (0.0)
Did you need to ask for help to read the informed consent form??	13 (23.2)	5 (8.9)	38 (67.9)

HBOT: Hyperbaric oxygen treatment, n: Number %: Row percentage. Two participants did not want to answer some of the questions on the informed consent checklist form, percentages calculated based on the number of participants who responded to each question.

risks and possible precautions to be taken as well as the expected benefits from the treatment in detail during the consent process.

Among the participants in our study, 94.6% stated that they wished to be informed about their health status, whereas 89.3% of them wanted to be informed about the diagnosis, and the treatment outcomes of the disease. Furthermore, 82.1% of the patients were curious about treatment methods, and 80.4% about additional treatment methods. Similarly, a study conducted by physicians at the department of orthopedics showed that nearly all patients (94.6%) consider it necessary to be informed about the diagnosis and the planned surgery as well.[16] Inferences from other studies in the literature and the results of our research clearly reveal that patients wish to be informed about diseases and treatment methods as much in detail as possible. The fact that informing patients about treatment adequately bears great importance as a legal requirement of current regulations and medical ethics.[2,9,10]

HBOT is a medical treatment that may appear difficult to understand both conceptually and visually in clinical practice. An accurate understanding of technical information and basic scientific concepts that are communicated clearly to the patient eases the preconception of the treatment. Thus, it is significantly important to elaborate on certain concepts such as the effects of pressure, the efficacy of oxygen, the number of sessions, and the toxic effects linked to oxygen during the treatment. In our study, the majority of participants (98.2%) stated that they were satisfied with the information received before HBOT. The

Table 4. Comparison of scale and form points according to gender and educational status

Scales and forms	Gender				p-value	Educational status				p-value
	Female		Male			Below high school		High school and above		
	Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)		Mean±SD	Median (Min-Max)	Mean±SD	Median (Min-Max)	
SMMT	25.1±3.2	25.0 (20.0–30.0)	27.1±3.2	29.0 (15.0–30.0)	0.048	25.0±3.5	25.0 (15.0–30.0)	27.9±2.4	29.0 (23.0–30.0)	0.001
DCS	11.6±12.0	7.8 (0.0–37.5)	12.9±17.6	6.3 (0.0–100.0)	0.992	16.3±21.2	11.7 (0.0–100.0)	9.1±8.7	5.5 (0.0–25.0)	0.264
SURE	3.9±0.3	4.0 (3.0–4.0)	3.9±0.3	4.0 (3.0–4.0)	1.000	3.8±0.4	4.0 (3.0–4.0)	4.0	4.0	0.027

SMMT: Standardized mini mental test; DCS: Decisional conflict scale; SURE: Decision certainty scale; SD: Standard deviation; min: minimum; max: maximum; p: Mann-Whitney U test.

response rate of the informed consent checklist form indicated that patients were positively affected by the information process. However, in answer to the question "Was there anything you did not agree with in the form you signed?" 16.4% said yes, while in answer to the question "Were there any words that you did not understand during the information process?" 14.6% said yes. This led to the consideration that even though some of the patients did not understand the information completely, they showed the tendency to sign the consent form. Moreover, these findings led us to consider that it may be useful and valuable to check the parts that the patient does not understand clearly in the form through a checklist form and to provide additional information.

Some researchers criticize that patient informed consent does not always show three main features such as adequate information provision, comprehension of provided information, and a voluntary decision.[17] This may affect significantly levels of satisfaction of the patient. There are various study results regarding satisfaction with information and giving consent after understanding the information in the literature. To illustrate, in one study, the results showed that 48% of the patients signed the consent without reading it, whereas 94% of the ones who read the consent, stated that the content of the consent consisted of incomprehensible medical and technical content.[18] In another study involving 371 patients, only 56% of patients had all their questions answered before the treatment and 20% of the participants were not satisfied with the information provided by the physician.[19] In a recent study, the overall satisfaction of patients with preoperative informed consent process was 70.3%.[20] Another important issue is explaining the name of the disease and treatment procedure comprehensively. In a study, it was found that 18% of patients did not know the name of the disease, whereas only 25% of patients knew the name of the surgical operation.[21] In a study conducted by Jukic et al., it was reported that only 11% of patients accepted being comprehensively informed and confirmed that they received sufficient information regarding the treatment.[22] In a review reported by Falagas et al., the degree of patients' comprehension of the informed consent for surgery and clinical research was evaluated. The authors found that, for surgery, the understanding of the information provided was 29% and the satisfaction from the amount of information was 58%.[23] Based on the results of all these studies, some researchers have come up with certain recommendations for the quality of consent documents to improve patient's comprehension and satisfaction.[24,25] Our study complies with other studies which indicate that, although there are different outcomes in terms of certain variables, the frequency of participants who did not understand the information cannot be underestimated. This situation bears the risk of violation of patient rights and malpractice.

When responses to questions on the checklist form were evaluated, most patients appeared to have gained information about topics such as disease diagnosis, treatment,

alternative treatment methods, and side effects during the information session before the treatment. However, around 10% and 20% of the patients who were reported claimed that they had not been informed about the prognosis, treatment method, additional treatments, and the outcomes of treatment. These results show that having provided the relevant aforementioned information, a significant amount of the information was understood by the patients. However, nearly one-fifth of the study group's comprehension of the fundamental informed consent components was low. According to some studies in the literature, the level of comprehension by the patients varies between 71 and 91%.[26-28] Ultimately, there is a necessity for additional methods to support the patients' understanding.

In fact, the physician and the patient should have a mutual understanding and agree with one another on the patients' autonomy and their decision-making process.[29] Interestingly, the patients answered the question "Who can make the best decisions about treatment?" in our study, and the most common response was "the doctors" at 53.6%. This mindset of patients may be due to the trust they put in the doctors and the fact that they feel incompetent in the decision-making related to their health status. For this reason, there may be certain points that require improvement in the consent form to inform the patients about HBOT. According to the research, it has been determined that it is crucial to do further study in order to transform "the doctor knows best" attitude into an approach based on the patient's autonomy and "shared decision-making."

In our research, an attempt was made to investigate the effect of mental status, decisional conflict, and certainty about decisions using the SMMT, DCS, and SURE scales, as well as the informed consent checklist form, was used. Whereas 1.8% of participants had moderate-severe cognitive disorder, 16.1% had mild cognitive disorder. 5.4% of patients tended to be uncomfortable with the decision and 7.1% experienced decisional conflict (SURE points ≤3). No statistically significant correlations were identified between the SMMT, DCS, and SURE scales. Gender was determined to affect SMMT, while educational status was determined to affect both SMMT and SURE scores. The high values on SMMT assessment for men are considered to be due to the educational level in society.

In addition, increased educational level positively affected the SMMT and SURE scores. In our research, while half of the men in the study group graduated from high school or above, only one-third of the women had an education level of high school or above. Therefore, men's SMMT scores were thought to be higher than women. Although there is a lack of research in terms of HBOT in informed consent process, the effect of education has been discussed and studied in other specialties in medicine. To illustrate, in a recent study in 2022, researchers reported that one-third of surgical patients' comprehension of informed consent was low for surgical management. Researchers concluded that several factors were associated with poor perception of surgical procedures: educational status, language, and poor knowledge. According to the authors, strategies to improve the awareness of patients should be put into practice.[30] Another compliance with our study is related to the literacy of the patients indicating that certainty about decisions decreases in patients who have not received adequate education.[2,3]

Limitation of Research

This study attempted to identify the quality of information given before HBOT, the level of understanding among patients, and factors affecting this situation. Although some of the study population stated, there were parts they did not accept on the informed consent form, they still provided signed consent. For this reason, it is necessary to investigate the data carefully. The selection of participants on the basis of volunteering and the small population makes it difficult to generalize the obtained results. The patient, whose minimum mental test result is below 19, shows moderate to severe cognitive dysfunction and we believe that his answers will not be reliable. It was thought that this patient and nine other patients with moderate SMMT results may have affected the statistics.

Conclusion

Although the content and adequacy of informed consent are still debated, malpractice cases may still be present in the field. The content of the informed consent form must be carefully organized to prevent malpractice cases related to informed consent and definitely to implement good clinical practices in HBOT. To our knowledge, the current research is the first study in the literature to show the crucial role of informed consent and the factors affecting comprehension as well as the decision of the patient undergoing HBOT. As a result, Underwater and Hyperbaric Medicine physicians must consider various aspects of the consent process to reduce the risk of malpractice and ensure good clinical practice.

Acknowledgement

Some data of this study were presented as a poster at the "43rd Annual Meeting Italy 12-16 September 2017" congress organized annually by the EUBS-European Underwater and Baromedical Society. Title of Poster "A survey study about informed consent of patients treated in Hyperbaric Oxygen Treatment Center: Medicolegal approach".

Ethics Committee Approval

This study approved by the Kartal Dr. Lutfi Kirdar State Hospital Clinical Research Ethics Committee (Date: 03.09.2015, Decision No: 89513307/1009/494).

Informed Consent

Prospective study.

Peer-review

Externally peer-reviewed.

Authorship Contributions

Concept: S.G.S., E.A.K., Ö.Ö.; Design: S.G.S., E.A.K.; Supervision: S.G.S., E.A.K.; Materials: S.G.S., E.A.K.; Data: S.G.S.; Analysis: S.G.S., E.A.K., Ö.Ö.; Literature search: S.G.S., E.A.K.; Writing: S.G.S., E.A.K., Ö.Ö.; Critical revision: S.G.S., E.A.K., Ö.Ö.

Conflict of Interest

None declared.

REFERENCES

1. Thom SR. Hyperbaric oxygen: its mechanisms and efficacy. Plast Reconstr Surg 2011;127:131S–41S. [CrossRef]
2. Shah P, Thornton I, Turrin D, Hipskin JE. Informed consent. [Updated 2022 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK430827/. Accessed Jun 8, 2023.
3. Fink AS, Prochazka AV, Henderson WG, Bartenfeld D, Nyirenda C, Webb A, et al. Predictors of comprehension during surgical informed consent. J Am Coll Surg 2010;210:919–26. [CrossRef]
4. Arshad MA, Omar N, Amjad Z, Bashir K, Irfan M, Ullah I. Perceptions and practices regarding the process of obtaining informed consent from surgical patients at a tertiary care hospital. Ann Med Surg (Lond) 2021;73:103195. [CrossRef]
5. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making 1995;15:25–30. [CrossRef]
6. Ferron Parayre A, Labrecque M, Rousseau M, Turcotte S, Légaré F. Validation of SURE, a four-item clinical checklist for detecting decisional conflict in patients. Medical Decision Making 2014;34:54–62.
7. Légaré F, Kearing S, Clay K, Gagnon S, D'Amours D, Rousseau M, et al. Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. Can Fam Physician 2010;56:e308–14.
8. Güngen C, Ertan T, Eker E, Yaşar R, Engin F. Standardize mini mental test'in Türk toplumunda hafif demans tanısında geçerlik ve güvenilirliği. Türk Psikiyatri Dergisi 2002;13:273–81.
9. Grauberger J, Kerezoudis P, Choudhry AJ, Alvi MA, Nassr A, Currier B, et al. Allegations of failure to obtain informed consent in spinal surgery medical malpractice claims. JAMA Surg (Electronic Journal) 2017;152:e1705444.
10. Kalkan EA. Analysis of the high court decisions on informed consent cases in Turkey from a forensic point of view. Journal of Scientific Perspectives 2018;3:125–34. [CrossRef]
11. Shirley E, Mai VH, Neal KM, Blake KV. Can a checklist improve the informed consent process? Cureus 2021;13:e13148. [CrossRef]
12. Demir Akça AS, Saraçlı Ö, Emre U, Atasoy N, Güdül S, et al. Relationship of cognitive functions with daily living activities, depression, anxiety and clinical variables in hospitalized elderly patients. Noro Psikiyatr Ars 2014;51:267–74. [CrossRef]
13. Çalışkan Z. Erken evre meme kanserli kadınlarda ameliyat tercihleri ve tercihleri etkileyen değişkenler. T.C. Ege Üniversitesi Sağlık Bilimleri Enstitüsü, yüksek lisans tezi; 2007.
14. Garvelink MM, Boland L, Klein K, Nguyen DV, Menear M, Bekker HL, et al. Decisional conflict scale use over 20 years: the anniversary review. Med Decis Making 2019;39:301–14. [CrossRef]
15. Yeşilçınar İ, Güvenç G. Karar vermede çatışma ve karardan emin olma ölçeklerinin Türk toplumuna uyarlanması. Hemşirelikte Eğitim ve Araştırma Dergisi 2019;16:87–95.
16. Aydın Er R, Özcan Şenses M, Akpınar A, Ersoy N. Ortopedide aydınlatılmış onama ait etik sorunlar: Kocaeli'den bir örnek. Turkiye Klinikleri J Med Sci 2011;31:455–63. [CrossRef]
17. Sherman KA, Kilby CJ, Pehlivan M, Smith B. Adequacy of measures of informed consent in medical practice: A systematic review. PLoS One 2021;16:e0251485.
18. Joolaee S, Faghanipour S, Hajibabaee F. The quality of obtaining surgical informed consent. Nurs Ethics 2017;24:167–76. [CrossRef]
19. Ochieng J, Buwembo W, Munabi I, Ibingira C, Kiryowa H, Nzarubara G, et al. Informed consent in clinical practice: patients' experiences and perspectives following surgery. BMC Res Notes 2015;8:765.
20. Ayele TT, Negash TT, Oumer KE, Mekuanint A, Teshome D, Fenta E, et al. Patients' satisfaction and associated factors towards preoperative informed consent process: A cross-sectional study. Ann Med Surg (Lond) 2022;79:104104. [CrossRef]
21. Kurt E, Ucar M, Atac A. Quality of an informed consent prior to a surgical intervention? experience of a teaching hospital. Pak J Med Sci 2016;32:206–10. [CrossRef]
22. Jukic M, Kozina S, Kardum G, Hogg R, Kvolik S. Physicians overestimate patient's knowledge of the process of informed consent: a cross-sectional study. Med Glas (Zenica) 2011;8:39–45.
23. Falagas ME, Korbila IP, Giannopoulou KP, Kondilis BK, Peppas G. Informed consent: how much and what do patients understand? Am J Surg 2009;198:420–35.
24. Jefford M, Moore R. Improvement of informed consent and the quality of consent documents. Lancet Oncol 2008;9:485–93. [CrossRef]
25. Schenker Y, Fernandez A, Sudore R, Schillinger D. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. Med Decis Making 2011;31:151–73. [CrossRef]
26. Bergler JH, Pennington AC, Metcalfe M, Freis ED. Informed consent: how much does the patient understand? Clin Pharmacol Ther 1980;27:435–40.
27. Song JH, Yoon HS, Min BH, Lee JH, Kim YH, Chang DK, et al. Acceptance and understanding of the informed consent procedure prior to gastrointestinal endoscopy by patients: a single-center experience in Korea. Korean J Intern Med 2010;25:36–43. [CrossRef]
28. Barrera AZ, Dunn LB, Nichols A, Reardon S, Muñoz RF. Getting it "right". J Empir Res Hum Res Ethics 2016;11:291–8.
29. Kalala WT. Patients' perceptions and understanding of informed consent for surgical procedures. Research report. Johannesburg: University of the Witwatersrand; 2011.
30. Bernat JL, Peterson LM. Patient-centered informed consent in surgical practice. Arch Surg 2006;141:86–92. [CrossRef]

Hiperbarik Oksijen Tedavisi Gören Hastalarda Bilgilendirilmiş Onam Hakkında Kesitsel Çalışma

Amaç: Bu çalışma ile, hiperbarik oksijen tedavisi (HBOT) uygulanan hastaların aydınlatılmış onam süreçlerinin değerlendirmesi, verilen bilgiyi anlamaları ve tedavide karar vermelerini etkileyen faktörlerin belirlenmesi amaçlanmıştır.

Gereç ve Yöntem: Bu kesitsel çalışma grubunu Sualtı ve Hiperbarik Tıp Kliniğine başvuran hastalar oluşturdu. HBOT planlanan hastalara süreç önce sözlü olarak anlatıldı ve ardından bilgilendirilmiş onam formu kendileri tarafından okunmasıyla tedavi hakkında bilgi verildi. Hastalara onam bilgileri verildikten sonra, kendilerine tanımlayıcı özellikleri belirten form, bilgilendirilmiş onam kontrol listesi, Standartlaştırılmış Mini Mental Test (SMMT) ve hastalarda kararda çelişkiyi ölçen testlere verilen yanıtlar değerlendirildi.

Bulgular: Çalışmaya 56 hasta katıldı. Yaş ortalaması 46.4±13.5 yıl olup, hastaların %75'i erkekti. Katılımcılar arasında, %5.4'ü karardan emin olmama eğilimindeydi ve %7.1'i kararda çelişki yaşadı. "Sizin için önerilen tedaviye karar verecek en iyi kişi kimdir?" sorusuna hastaların %53.6'sı "doktor" olarak yanıtladı. Çalışmada kullanılan ölçek ve formların sonuçları değerlendirildiğinde, cinsiyet ve eğitim düzeyi açısından karşılaştırıldığında, cinsiyete göre SMMT (0.048) puanları, eğitim durumuna göre SMMT (0.001) puanları ile karardan emin olma testi (0.027) arasında farklılık istatistiksel olarak anlamlı bulundu.

Sonuç: Bu araştırma, HBOT uygulanan hastalar için aydınlatılmış onamın önemini ve kararla beraber verilen bilgiyi anlamayı etkileyen faktörleri gösteren literatürdeki ilk çalışmadır. Malpraktis riskini azaltmak ve iyi klinik uygulamaları için Sualtı Hekimliği ve Hiperbarik Tıp doktorları tedavi planladıkları hastalarının onam sürecinin çeşitli yönlerini değerlendirerek yürütmelidir.

Anahtar Sözcükler: Aydınlatılmış onam; bilgi; hiperbarik oksijen tedavisi; karar; mini-mental test.