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INFORMED CONSENT OF COUPLES IN IVF PRACTICES: A LIMITED STUDY IN TURKEY

TÜP BEBEK UYGULAMALARINDA ÇİFTLERİN AYDINLATILMIŞ ONAMI: TÜRKİYE'DE SINIRLI BİR ÇALIŞMA

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Abstract

Objective: The aim of this study is to obtain informed consent in vitro fertilization applications and to determine the factors affecting this process.
Methods: This article is a full-text original research article. Descriptive and cross-sectional study was conducted with 193 women and 54 men, undergoing in vitro fertilization treatment. Study form consisted of questions regarding sociodemographic features and informed consent. The form was filled on the day the eggs were collected. The ethical committee approved the protocol of the study and all participants were provided with verbal informed consent.
Results: According to result of the study, it was found that more than one third (38.5%) of the participants were not informed verbally, 34.1% of those who were informed could not understand what was told. Those who applied to a private physician were more informed. The explanations were not understood mainly due to the problems arising from informing process. The consent form was given to all participants after starting treatment. Two thirds of the participants read the consent form and 22.7% of them did not understand what they read. Almost half (41.3%) of those who did not read the consent form stated that they consider the reading and signing the form as a procedure for the implementation of the transaction. Those who had time to read the consent form read more ($p<0.001$) and understood more ($p=0.036$).
Conclusion: In this study, it was concluded that there were problems with the transferring and understanding of information, and that valid consents were not taken from some patients.

Keywords: *Medical ethics, informed consent, in vitro fertilization, infertility.*

Öz

Amaç: Bu çalışmanın amacı, tüp bebek uygulamalarında aydınlatılmış onam elde edilmesi ve bu süreci etkileyen faktörleri belirlemektir.
Yöntem: Bu makale tam metin özgün bir araştırma makalesidir. Tanımlayıcı ve kesitsel araştırma tüp bebek tedavisi gören 193 kadın ve 54 erkek ile yapılmıştır. Çalışma formu, sosyodemografik özellikler ve aydınlatılmış onam ile ilgili sorulardan oluşmuştur. Form, yumurtaların toplandığı gün doldurulmuştur. Etik kurul, çalışmanın protokolünü onaylamış ve tüm katılımcılardan sözlü bilgilendirilmiş onam alınmıştır.
Bulgular: Araştırmanın sonucuna göre, katılımcıların üçte birinden fazlasının (%38,5) sözlü olarak bilgilendirilmediği, bilgilendirilenlerin ise %34,1'inin anlatılanları anlayamadığı tespit edildi. Özel doktora başvuranlar daha fazla bilgilendirilmiştir. Açıklamalar, başlıca bilgilendirme sürecinden kaynaklanan sorunlar nedeniyle anlaşılamamıştır. Onam formu tüm katılımcılara tedavi başladıktan sonra verilmiştir. Katılımcıların üçte ikisi onam formunu okumuş ve %22,7'si okuduğunu anlamamıştır. Onay formunu okumayanların yaklaşık yarısı (%41,3) formu okumayı ve imzalamayı işlemin uygulanması için bir prosedür olarak gördüğünü belirtmiştir. Onam formunu okumak için zamanı olanlar daha çok okumuş (p<0,001) ve daha çok anlamıştır (p=0,036).
Sonuç: Bu çalışmada bilgilerin aktarılmasında ve anlaşılmasında sorunların olduğu, bazı hastalardan geçerli onam alınmadığı sonucuna varıldı.

Anahtar Kelimeler: *Tıp etiği, aydınlatılmış onam, tüp bebek, kısırlık.*

Introduction

It is important to obtain informed consent from patients in order to establish trust in the patient-physician relationship, to ensure ethical and legal validity of medical interventions, to increase patient satisfaction, to maintain patient-centered work and to improve the quality of care.[1] Informed consent with legal, medical and bioethical aspects requires mutual discussion about the risks, benefits and options of the procedures and treatments to be applied. Thus, patients' rights are protected and their autonomy is respected.[2] Although there are legal developments regarding obtaining informed consent from patients, it has been shown that patients do not have enough information to decide on treatment.[3,4] Although there have been many studies on informed consent in different fields, there are few studies on obtaining informed consent from people undergoing in vitro fertilization (IVF) treatment, which is one of the most important medical developments of the last century. In some of these studies, historical consent forms were examined.[5,6] According to the results of the studies patients are informed less and less over time, consent forms are long and detailed, written in a language that patients cannot understand, and their content is not found sufficient by patients. In these studies, it was found that some of the patients did not read the entire form, those who read it did not pay attention, most of what was written on the form was not remembered by the patients, and some patients did not believe that the consent form was important.[5-7] It is claimed that women and their spouses are treated without knowing and understanding the effects of IVF, one of the Assisted Reproductive Technology (ART) techniques on the health of women and their unborn children.[2] Although obtaining informed consent is important in all treatments and interventions, it is considered to be more important in IVF treatment because the treatment is not urgent, there are multiple options for treatment and there are medical risks.[2, 8-12] It is stated that IVF treatment has many risks such as redness and swelling at the injection site, nausea due to drugs, headache, mood changes, failure to conceive at the end of the treatment, multiple pregnancy, ectopic pregnancy, miscarriage, premature birth in case of pregnancy.[8,13] The first regulation on IVF in Turkey was published in 1987. With this regulation, couples applying for IVF should fill out and sign the consent document deriving from the Regulation on In Vitro Fertilization and Embryo Transfer Centers. The regulation was revised in 2010 and 2014. With the last regulation the informed consent information has been made more detailed. The preparation of the informed consent form in Turkey is left to IVF centers. However, its content is expected to comply with the patient rights legislation. In order to ensure that it is read according to the regulation, the consent form must be given the day before starting the treatment and must be read orally by the central officer. The couples are also asked to sign both by handwriting, "I have been adequately informed about the application in all matters, including multiple pregnancy and failure, both verbally and in writing" [14]

This study was carried out in order to determine the problems and their causes of the informed consent process in widely applied in vitro fertilization practices, that are very important for couples all over the world, and to propose solutions to the problems in the area.

Methods

The research was conducted at the university hospital in Kocaeli, Turkey. The hospital where the study was conducted is a public hospital in which both paid and free treatments are provided. There is no patient limitation. Patients apply to the hospital in two ways: Firstly, those who applied to the polyclinic were examined without paying a fee, but could not choose their physician. Secondly, those who apply to a private physician pay only the first examination fee and can choose their physician.

It is planned that the study will be carried out in the summer, foreseeing that working couples will be treated in a more comfortable period. The study conducted between June 2018 – September 2018 was terminated when similar answers started to be received. Total 246 couples applied to the IVF unit to collect eggs and sperm samples during study period. The women who did not want to participate in the study, those who came to be treated for the second time during the study period, those who could not communicate because they did not speak Turkish, and those who received anaesthesia before completing the study form were not included in the study. The men who left the unit immediately after giving sperm and those who did not want to participate in the study were also not included in the study. The study was completed with the participation of 78.4% of the women and 21.9% of men that originally joined to the study.

The study form was prepared by the researchers. Expert opinions were taken for the study form developed as a result of the relevant literature review. Pre-application was made with women who had undergone IVF treatment before and it was understood that the form was understandable. The questions in the data collection form were asked to both women and their spouses.

The day of egg collection was determined for the application of the study form since all of the couples under treatment could be interviewed. The form was filled out by women on the day the eggs were collected, before the procedure. Men were filled out the form after giving the sperm sample, while waiting for their spouses in the waiting room. Firstly, the purpose of the study was explained to all participants. Participants who did not read the consent form were given the form to read beforehand. Then they were asked to fill in the form by giving the study form and a pen. Since only the question about risks was based on memory, it was asked and recorded by the researcher. It took approximately 10 minutes to complete the study form and read the consent form. The question about the risks of treatment was asked by the researcher in an empty room to prevent other participants from hearing.

First of all, the permit numbered 2018/169 was obtained from the institution where the study was conducted and Kocaeli University Non-Interventional Clinical Research Ethics Committee on 2018. The purpose of the study is written at the top of the study form, where the credentials will remain confidential, and there will be no problems in applying their current and future treatments if they do not participate in the study. The text was also explained verbally by the researcher. No pressure or coercion was applied to the couples to participate in the study.

SPSS 20 package program was used to analyze the data. Continuous variables are expressed as mean ± SD (standard

deviation), while categorical variables are expressed as numbers and percentages. The relationship between dependent and independent variables was compared with chi square test $p<0.05$ was considered statistically significant.

Results

The average age of the men and women in the study was 34.05 ± 5.91 and their ages ranged from 21 to 50. More than a third a had university degree and above, and 27.5% had a minimum wage or lower income. More than half of the women were receiving IVF for the first time and most of all applied to a private physician to be treated. Most of the women and their spouses (89.5%) decided to be treated together and stated that they wanted to have children to experience maternity and paternity.

In the study, 61.5% of the participants were verbally informed about the treatment. Patients who applied to a private physician were more informed (72.5%), the information was given by mutual conversation (79.3%) and visual aids (92.3%), directly by the physicians (79.5%). More verbal information was given to women (78.9%) than men, and the explanation was given by both physicians and nurses (59.9%) 71.4% of men were not informed (Table 1).

Table 1: The assessment of verbal informing process

Informing Status (n=247)	n(%)	*p*
I was informed	152 (61.5)	Gender *p*=0.000 Reference place *p*=0.000
I was only told that when I will come and what kind of treatment I will have	74 (30.0)	
No information was given	21 (8.5)	
Who did the oral information? (n=226)*		
Physician and nurse	118 (52.2)	Gender *p*=0.000,
Physician	78 (34.5)	Reference place *p*=0.005
Nurse	30 (13.3)	
Type of verbal information (n=256)**		
Face to face talking	198 (77.3)	Reference place *p*=0.010, Gender *p*=0.041
Informed with visual tools	26 (10.3)	Reference place *p*=0.044, Gender *p*=0.031
Dialogue was established unilaterally, I just listened	16 (6.2)	
Only questions that I asked were answered	16 (6.2)	

*Since 21 people stated that they were not informed verbally, the answers given to questions about verbal information were evaluated over 226 people. ** In this question, participants marked more than one item.

Most of the patients (69.8%), who found the information period sufficient, understood all the explanations. Those who did not understand the information stated that too much information was given in a short time (40.5%), that they could not focus on what was told due to stress (39.2%),words that they could not understand (12.7%) were used and the explanations were insufficient (%7.6). More than half of the participants (65.9%) found the time in which the information was disclosed appropriately, and 75.5% found the environment in which the information was disclosed appropriately. However, those with high income (22.8%) and those who had undergone IVF treatment before (45.7%) did not find the environment in which the information was given appropriate. Those who were examined by paying a fee were able to ask more questions they wanted to ask ($p<0.001$).

A significant portion of the participants (79.2%) were satisfied with the given information. Those, who understood all the information explained and who found the content of the explanations and the duration of the explanation sufficient, were more satisfied. Some of the patients made suggestions about verbal information. The suggestions were to be treated by the physician of their choice at every stage of the treatment, to allow more time for verbal explanations, to be able to ask their questions easily, to inform the men as well, to inform them by using visual tools and not to use medical vocabulary during these informatory sections (Table 2).

Consent forms were given to the patients by the secretary (80.6%) on the day when the egg was fully mature (67.6%) and received back two days later, on the morning of the egg collection. Consent form was given to some patients (9.3%) just before egg collection and they were asked to sign it. Three quarters (%75.7) of the participants read the consent form. Most of the patients (87%), who were given the consent form just before the egg collection process, did not find the time sufficient to read the form. When compared to men, women read the consent form more. University graduates and those who were given a consent form on the day the egg matured read the form very carefully. Those who did not read the consent form stated that they had no choice but to receive treatment in order to have a child at most (63.5%). It was seen that more than half of the participants (77.3%) understood what they read in the consent form (Table 3). Participants with high income and education stated that they understood all or most of the consent form. The participants suggested that they preferred the consent form be short and concise (29.5%), no medical vocabulary used (24.0%), first the physician explain what was written on the form (19.2%), the risks to be expressed more gently (18.0%) and inclusion of more explanatory information (9.4%) (Table 3).

In the study, the researcher first asked the participants what they remembered about the risks and complications of the treatment from the explanations made and the information they read in the consent form. Almost half of the patients (40.9%) remembered that the risk of death was the highest. Few patients (10.5%) did not remember any risk of treatment. The researcher then read to the patients about the risks and complications of treatment and then asked them to count the risks and complications. The participants were able to count at least one of the risks and complications of

the treatment and remembered that the pain could be the most.

When the participants in our study were asked if they would like to know the risks and complications of the treatment, the majority (77.3%) stated that they wanted to know. Almost all (94.6%) of those who did not want to know the risks and complications stated that they did not want to know in order not to be affected psychologically and to avoid negative results of the treatment. Some participants (44.4%) accept all the risks and complications of having a baby (Table 4).

Table 2: The evaluation of participants' understanding the verbal information (n =226) *

Understanding the verbal information	**n(%)**	***p***
I understand all information given	149 (65.9)	
I understand most of information given	62 (27.4)	Information period *p=0.030*
I understand some of information given	15 (6.7)	
Was the environment in which verbal information was given appropriate?		
Yes	171 (75,7)	Income *p=0.026* Number of treatments *p=0.027*
No	21 (9,3)	
Partially	34 (15,0)	
Asking questions during information		
Yes	189 (83.6)	
No	5 (2.2)	Reference place *p=0.000*
Partially	32 (14.2)	
Satisfaction with the information		
Yes	179 (79.2)	Verbal information *p=0.000* Understanding verbal information *p=0.003* Adequacy of information *p=0.005* Duration of meeting *p=0.000*
No	5 (2.2)	
Partially	42 (18.6)	

*Number of participants who stated that they were informed verbally.

Table 3: Giving consent form, reading and understanding by the participants (n=247)

Status of reading the consent form	**n(%)**	***p***
They read	187(75.7)	Gender *p=0.05*
The researcher had it read	60 (24.3)	Time to submit the form *p=0.000*
How carefully did you read the consent form?		
I did not read carefully at all	11 (4.5)	
I read carefully	140 (56.7)	
I read very carefully	96 (38.8)	Educational status *p=0.032* Form submission time *p=0.021*
Did you understand what was written on the consent form?		
Yes	191(77.3)	Time to submit the form *p=0.036*
No	56 (22.7)	
How much of what was written on the consent form did you understand?		
Most/All	215(87.0)	Income *p=0.000* Income *p=0.002*
Very few	32 (13.0)	

Table 4: Participants' desire to know the risks of IVF treatment and their status of being affected (n=247)

Desire to know the risks of IVF treatment (n=247)	**n(%)**
I would like to know	191(77.3)
I don't want to know	56(22.7)
Reason for not wanting to know risks (n=56)	
Not being psychologically affected	53 (94.6)
Knowing the risks will not work for me	3 (5.4)
How did knowing the risks affect you (n=486)*	
I take all the risks to have a baby	216 (44.4)
It made me make conscious decisions about the interventions	136 (28.0)
I scared	79 (16.3)
My confidence to my physician was increased	55 (11.3)

*Participants declared more than one opinion.

Discussion

Informed consent is important for both ethics and human rights and necessary in every culture. The New Zealand Assisted Reproductive Technology Advisory Committee (ACART) has stated that informed consent must be obtained before individuals apply for assisted reproductive technologies (ART).[15] Prerequisite for informed consent is access to information.[16] There are many written information documents on assisted reproductive techniques and IVF treatment on the internet. However, it is argued that verbal information is important, even more effective than written information, in order to establish a relationship of trust between the patient and the physician, and to enable patients to ask their questions and understand them better.[3,17,18] However, it has been shown in studies that verbal information was not given to the patients or it was not done at an adequate level. It was observed that 34% of surgical patients in Saudi Arabia[19] 20.6% of orthopedic patients in Turkey[20], and 13.6% of patients undergoing cardiac surgery[21] were not informed. The findings of the studies show that there is a decrease in the proportion of uninformed patients in Turkey and also in other countries. However, the consent of some participants without being informed suggests that the ethical and legal rights of all patients were not protected. [22,23]

In our study, 38.5% of the patients who received IVF treatment were not informed. The high rate of patients who were not informed verbally in our study may be due to the different patient groups. IVF treatment has a different process and features than other treatments. At least two people must be informed and signed the consent form. In this respect, informing women and men together in IVF treatment may be different from informing only the patient himself, as in surgical treatment. Obtaining informed consent may be more complicated than other treatments, since in vitro fertilization treatment has multiple stages and needs to be informed at each stage. However, it is stated that the informed consent should comply with the general standards.[22]

In our study, there were differences in terms of informing male and female participants. More information was given to women. The reason men were less informed may be that they do not participate in every step of the treatment process, but only come to give a sperm sample. Especially in Muslim countries, childbearing has an important value in the family.[24] Infertility problem is generally seen as the failure of the woman and the inability of the man to fulfill his role in society.[12] For this reason, although the of infertility is caused by men, women usually go to treatment.[25] Men read the consent form less than their spouses, despite their signatures. This result suggests that although they stated that they decided to have children together, men put the burden of the process on women. Women have to decide also on the behalf of their partners during treatment, which can have many side effects. In our study, women stated that their husbands should also be informed. It may be helpful to remind men that they have a responsibility to participate in treatment.

In our study, the first place of application for treatment affected to be given verbal information or not. Patients who applied to a private physician by paying a fee for the first examination were informed more and with visual tools that would facilitate understanding. In a study conducted in Iran, similar to our findings, it was found that patients who underwent surgery by paying a fee were better informed.[4] This suggests that more time is allocated to patients who receive services for a fee.

In our study, more than half (52.4%) of those informed by the nurses were patients who did not pay for the first examination. It is recommended that informing and obtaining consent should always be done by the people who perform the treatment.[15,23] However, it is accepted that health professionals who have received training on the relevant subject can also provide information.[23] In our country, informing the IVF patients is the responsibility of the physician.[14]

In our study, 93.3% of the participants understood all or most of what was explained, especially the participants who found the information period sufficient to understand more. The information explained could not be understood mostly due to the problems related to the presentation of the information, only the inability to understand only due to stress (39.2%) was caused by the patients themselves. Although patients are excited and anxious in IVF treatment, it is suggested that they can understand when the information is explained appropriately.[15,26]

The environment, in which the information is given, can be another factor that affects the understanding of information. Participants with high incomes and previous IVF experience did not find the environment as convenient ($p=0.028$). In a study conducted with patients undergoing IVF treatment in Israel, patients with higher income were less satisfied with the physical environment.[27] In the public hospital where our study was conducted, there is no patient limitation and the unit is crowded. It is important for patients to be able to ask questions in order to understand the information during the informatory process.[28] According to the results of several studies, the ratio of people who can ask their questions during verbal information varies between 39% and 84.8%. In our study, most of the participants (83.6%) stated that they could ask questions and this rate has a positive feature in terms of being at the upper limit of the rates in other studies.

In our study, it was found out that the patients were more satisfied with the informing process when sufficient verbal information was provided ($p<0.001$), when sufficient time was allocated for information ($p<0.001$), when the participants found the information sufficient ($p= 0.005$) and when patients understood what explained to them ($p=0.003$).

During the informed consent process, written information forms and consent forms are also used in addition to verbal information.[28,29] Consent form is a document that shows that the patient has approved the medical intervention and authorized the physician.[16] Consent forms should be written in short, familiar words, explain in parentheses if medical terminology is required. Sentences should be less than 12 words and paragraphs should be less than 7 lines.Consent forms should be consisted of an average of 12 pages, and written at the 8th grade reading level.[17] The hospital, where our study was conducted, does not have a separate information form. There are written explanations on the first pages of the consent form. The information in the consent form was insufficient. With this form, the text has the characteristics of a consent form rather than an information form. The number of words and sentences (996 words, 63 sentences) in the consent form used in our study was quite high. It was determined that the consent form was a "difficult" readable text.

During our study, we determined that most of the participants (75.7%) had read the consent form. In a study conducted in the United States with patients undergoing IVF treatment, it was found that 82% of the patients[7], and in another study[6] two-thirds of the patients read the consent form. In the study conducted with patients in surgery departments in Iran and Italy, the rate of reading the consent form was 48% and 51.8% respectively.[4,18] In our study it was seen that the rate of reading the consent form was higher than the studies conducted with surgical patients, and was similar to the studies conducted with those who are receiving IVF treatment in the USA. This result shows that patients undergoing IVF treatment are eager to learn more information than patients in surgical clinics.[2] Consent forms are forms that provide information to patients. However, the fact that the forms were not understood by all the participants suggested that the patients who were not given verbal information did not know what they signed. And this condition may lead to ethical and legal problems. It may be useful to read and test the comprehensibility of the information texts in the consent forms. The most common reason (41.3%) of the participants for not reading the consent form was that "the form is a procedure, they will be treated whether they read it or not, and they have no other choice". In other studies with IVF patients, it was determined that the participants gave similar responses.[6,30] These results showed that nearly half of the participants are considering the process of reading the consent form as a procedure.

In our study, the time of delivery of the consent form to the patient revealed a significant difference in terms of reading and understanding the form. The highest intelligibility was achieved when it was given at injection process that allowed the follicles to migrate into the abdominal cavity, where patients had two days to read the form. In IVF treatment, consent forms should be delivered one day before starting the treatment.[14,31] Pre-treatment for IVF implementation means "the time before hormone therapy application started" but none of the participants were given a consent form during this period. Delivering and having signatures on the forms to all participants at the end of the treatment may be due to the fact that the health workers also saw informed consent as a procedure. In our study, nearly half (43.6%) of the participants (n=23), whose consent form was given on the morning of the follicle collection process, stated that they did not understand or partially understood what they read. Another reason why the consent forms were not understood may be that the consent forms used in the hospital where the study was conducted were difficult to read.

In our study, the participants remembered the risk of death mostly, before the reminder. This may be due to the fact that the risk of death during treatment is written in four different places on the consent form.Of the participants 10.5% could not count any risks and complications of the treatment, during the pre-reminder process. In the studies conducted with different patient groups, it was found that 40% of general surgery patients and 56% of patients who received a blood transfusion, did not know the risks and complications.[3,32] More awareness of risks and complications in our study may be due to the fact that vitro fertilization treatment is different than other treatments and due to the developments on informed consent form. It was declared that learning the risks related to treatment may cause anxiety level to increase in patients and may negatively affect the treatment process. In some studies, it was found that being informed about the risks of treatment increased anxiety level in patients.[33] However, informing the patients about risks decreased the anxiety level according to other studies.[18,34,35] In our study, the participants who did not want to know the risks explained the reason for not wanting to know as "not being psychologically affected". The anxiety status of the participants was not measured with a separate tool. However, these findings showed that a group of participants were negatively affected by being informed, but did not abandon the treatment.

Conclusion

In our study, it was observed that not all of the participants gave valid informed consent. There were problems with the delivery and understanding of information. Mostly a valid informed consent could not be obtained most probably due to the problems arising from the healthcare professionals. The approval of the patients was taken after starting treatment, even at the end of the treatment. When receiving informed consent, the individual characteristics of patients such as education level were not taken into consideration.

It is recommended to inform all couples who will undergo IVF treatment in accordance with their needs, by allocating sufficient time, considering that their anxiety levels may be high, reorganizing the consent form as an easy-to-read text, and providing additional written information such as books and leaflet or manual that would make it easier to understand for people with low education level.

Limitations

This study was carried out in a single center. This may have negatively affected the representativeness of the findings.

Conflict of Interests

The authors declare no conflict of interest.

Compliance with Ethical Statement

Permit numbered 2018/169 was obtained from the institution where the study was conducted and Kocaeli University Non-Interventional Clinical Research Ethics Committee on 2018.

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Author Contributions

Study idea/Hypothesis: PS, MS; Data collection: PS; Data analysis: PS; Manuscript writing: PS, MS; Critical review: PS, MS

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