



Evaluation of the quality of informed consent in patients referring to infertility centers of Rasht in 2019

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Abstract

Introduction: Infertility refers to couples' inability to get pregnant after at least one year of intercourse without the use of contraceptives. Getting an informed consent as one of the principles of patients' rights, is a process that she decides on therapeutic intervention after receiving adequate information from the therapist team. The lack of understanding and compliance with this process today has involved many physicians and other medical staff and hospital practitioners in the legal and regulatory authorities.

Purpose: The aim of this study was to explain the quality of the informed consent process of patients Referred to infertility treatment centers in Rasht 1398.

Materials and Methods: This study is a cross- sectional and analytical study on 172 patients referred to Alzahra infertility center in Rasht in the first half of year 1398. Patients information were collected from a questionnaire. Then data were analyzed by SPSS. Mean and standard deviation indices with 95% confidence interval were used to describe the data and Shapiro- Wilk test and Spearman's rank correlation coefficient were used for data analysis.

Result: The mean score of "providing information to the patient" with a mean of 7.23 in intermediate condition, the mean score of "understandable consent form" with 3.51 out of 4 in excellent condition and the mean score of "communicating with the physician" with an average of 9.81 were good but the "voluntary consent form" with a score of 0.6 out of 8 showed this dimension to be weak. Overall, the quality of consent of patients referred to infertility centers in Rasht with average score of 21.16 was estimated. Only weak significant relationship was found between the level of educators' satisfaction with the quality of informed consent.

Conclusion: The quality of providing information and how to get a written consent was intermediate. Therefore, it is necessary to elaborate on other available therapies and their benefits and potential complications.

Keywords: Infertility, Informed consent, Quality, Get pregnant

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Received: 2021.05.10, Accepted: 2021.06.13

Introduction

Infertility refers to a couple's inability to get pregnant after at least one year of intercourse without the use of contraceptives (1). According to the World Health Organization (WHO), 10 to 15 percent of couples in the world (more than 80 million) suffer from infertility (2) and in Iran, about a quarter of Iranian couples experience primary infertility during their life of marriage (3).

Patients, as one of the socially vulnerable groups, are supported by a set of laws aimed at observing the physical, mental, spiritual, and social needs of the patient, which are called patients' rights (4, 5). And one of the issues in the new rights of patients is the issue of informed consent in medical practices (6).

Informed consent is the process by which a patient or legal representative understands and agrees to a treatment plan (7). Self-informed consent includes the three basic components of information sharing, decision-making ability, and the ability to make free and voluntary choices (8).

Among the undeniable reasons for the need for informed consent as part of the patient's rights, there is a significant relationship between obtaining the desired informed consent (consent with sufficient awareness) and obtaining the appropriate clinical outcome including improving mental health, relieving symptoms and pain, improvement in patient's function, and physiological criteria (9). The main purpose of obtaining consent is not to reduce the physician's responsibility but to help the patient make the best decision (10).

The lack of understanding and observance of this process today has involved a large number of physicians and other medical and hospital staff and has caused a lot of material and moral damage (11, 12).

Among the studies conducted in this field are the study of Barzegar and his colleagues, which examined the level of awareness of consent obtained from patients undergoing gynecological surgery at Hazrat Zeinab Hospital in Shiraz in 2016. According to the information obtained, 43.5% of patients had an inadequate understanding of the information provided to them. The number of information patients had about their rights in the hospital and the amount of reading the consent form was in the most inappropriate

situation. The findings of this study indicate the inadequate status and low awareness of consent obtained from patients undergoing gynecological surgery in Hazrat Zeinab Hospital (13).

Also, in another study, Meysami and his colleagues conducted a descriptive-analytical study on 120 people to explain the quality of the informed consent process of patients admitted to the surgical wards of a military hospital in Tehran and provide solutions to improve it in 2016. In this study, a questionnaire in the form of 19 questions was used. In evaluating the quality of informed consent of patients admitted to surgical wards, the average score of "providing information" with 18.93, "observing patients' decision-making competence" with 7.48, and "how to obtain written consent" with 5.47, is lower than the expected mean and mean scores of "Patient Perception" with 9.77, "Patient volunteering" with 8.16 and "Physician-Patient Interaction" with 16.02 were acceptable. In this study, the quality of the presenting information and the way of obtaining written consent was lower than expected and the mean score of patients' understanding, being volunteer, and interaction between physician and patient was acceptable (14).

So far, no study has focused on the quality of consent obtained from patients referred to infertility centers. This study examines the quality of informed consent of patients referred to infertility centers in Rasht.

Materials and Methods

The present study is a cross-sectional analytical study that was performed on patients referred to Al-Zahra Infertility Center in the first 6 months of 1398. The sampling method was simple random and the information of this study was collected using a questionnaire attached at the end of this thesis, as a self-report. This questionnaire has been used in Sheikh Taheri's study on hospitalization procedures under surgery (33). The validity of the questionnaire was assessed using the content application method and with the opinion of 10 professors and experts of the university, whose CVI value was 0.9 and its CVR was 0.8. The reliability of the questionnaire in the present study using the Cronbach's alpha method after completion by 35 people who refer to infertility centers in Rasht is 0.87.

This questionnaire has two parts. The first part includes demographic information of patients such as age,

waiting time for fertility, education, religion, and their number of marriages, and the second part (main) includes 22 questions in 4 areas of providing information to the patient, comprehensibility of the consent form, voluntary and doctor's interaction with the patient. The questions' scores are based on the answers yes (2 points), to some extent (1 point), and no (zero score). "No answer" or "I do not remember" answers are not rated. The total score of the questionnaire is 44-0. Thus, the score range of the questions was related to provided information (0-18), comprehensibility of the consent form (0-4), physician-patient interaction (0-14), and voluntariness (0-8). Scores below 25% are considered poor, between 50-25% are average, between 75-50% are good, and more than that are excellent. To collect data, after attending infertility treatment centers, we introduced ourselves to the recipients of infertility services and stated the purpose of this study and the method of work, and after obtaining their consent and assuring them about the preservation of the information, the questionnaires were completed by interview and we explained each question to the patient when needed.

The sample size with 95% confidence interval and the values ($d = 0.15$ p) and $pi = 50\%$ related to the consent form and using the following formula, 172 were estimated.

Results

In this study, 172 infertile women who were referred to the infertility center of Al-Zahra Hospital in the first 6 months of 1398 were studied. The minimum age of participants in this study was 20 years and the maximum was 46 years with a mean and standard deviation of $32 \pm 5/48$ years. The mean waiting time for fertility was $3/85 \pm 5/6$ years. Most participants (43%) had a diploma. All participants in this study (100%) were Shia. Among them, 167 people (97.1%) had their first marriage and only 5 people (2.9%) had their second marriage.

In terms of providing information to the patient, according to Table 1, most people (43.9%) stated that not enough information was available to them. Although most patients were satisfied with the information they received about the cause of infertility (61%), the method of infertility treatment (58.1%), and the cost of their treatment (68%), they mainly believed in the legal and jurisprudential aspects (68%), benefits (45.9%), side effects of treatment (50.6%), the reason for choosing treatment (43.6%) as well as other treatment options (77.3%) did not receive an explanation. In total, the average score of providing information was 18 points ($3/194 \pm 7/23$), which showed that the status of providing information to patients was moderate.

Table 1. Consenters' opinions about providing information in the process of obtaining consent in patients referred to infertility centers in Rasht in 1398.

Questions	Yes	To some extent	No	I Don't Remember	No Answer	Total
Explain the cause of infertility	105(61)	44(25.6)	23(13.4)	-	-	172
Explain the method of infertility treatment	100(58.1)	49(28.5)	23(13.4)	-	-	172
Explain the legal aspects of treatment	2(1.2)	3(1.7)	117(68)	42(24.4)	8(4.7)	172
Explain the jurisprudential aspects of the treatment method	2(1.2)	3(1.7)	117(68)	42(24.4)	8(4.7)	172
The benefits of the treatment method	41(23.8)	50(29.1)	79(45.9)	2(1.2)	-	172
Side Effect of treatment	30(17.4)	52(30.2)	87(50.6)	3(1.7)	-	172
The reason for choosing this method of treatment	65(37.8)	31(18)	75(43.6)	1(0.6)	-	172
Explaining other treatment options	20(11.6)	18(10.5)	133(77.3)	1(0.6)	-	172
The cost of this treatment	120(69.8)	24(14)	26(15.1)	2(1.2)	-	172
Total	485(31.3)	274(17.7)	680(43.9)	93(6)	16(1)	1548

* The numbers in parentheses indicate the percentage.

According to Table 2, most of the consenters for infertility treatment (84.3%) mentioned that the consent form was understandable for them. In general, the average score in terms of comprehensibility of the

consent form was $(1/172 \pm 3/51)$ out of 4 points), which indicates the excellent comprehensibility of the consent form.

Table 2. Consenters' opinions about the comprehensibility of the infertility treatment consent form in infertility treatment centers in Rasht in 1398.

Questions	Yes	To some extent	No	I Don't Remember	No Answer	Total
Adequacy of explaining the contents of the consent form	144(83.7)	12(7)	4(2.3)	9(5.2)	3(1.7)	172
Understanding the information of the consent form	146(84.9)	12(7)	2(1.2)	9(5.2)	3(1.7)	172
Total	290(84.3)	24(7)	6(1.7)	18(5.2)	6(1.7)	344

In terms of voluntary consent, only 4.2% of the participants in the study considered the choice of treatment to be voluntary. Most of the consenters stated that the benefits (89.5%) and side effects of other

available treatments (87.8%) were not explained to them. In total, a score of $1/383 \pm 0/6$ out of 8 points, showed that the status of obtaining consent is poor in terms of volunteering (Table 3).

Table 3. consenters' opinions about the voluntary process of obtaining consent in patients referred to infertility centers in Rasht in 1398.

Questions	Yes	To some extent	No	I Don't Remember	No Answer	Total
Awareness of the possibility of withdrawal from treatment	2(1.2)	6(3.5)	142(82.6)	19(11)	3(1.7)	172
Possibility to choose other methods	16(9.3)	14(8.1)	139(80.8)	3(1.7)	-	172
Explaining the benefits of other treatments	5(2.9)	12(7)	154(89.5)	1(0.6)	-	172
Explaining the side effects of other treatments	6(3.5)	14(8.1)	151(87.8)	1(0.6)	-	172
Possibility to choose other methods	29(4.2)	46(6.7)	586(85.2)	24(3.5)	3(0.4)	688

As Table 4 above shows, the majority of consenters (56.2%) reported having a good physician relationship with them. Most patients reported trust in the physician (88.4%), comprehensibility (72.7%), and simplicity of physician explanations (73.8%), but 55.2% of people stated that they could not contact the doctor. In total, a score of $3/411 \pm 9/81$ out of 14 points indicates that the physician's relationship with patients was good.

There was no statistically significant relationship between the quality of informed consent and age and waiting time for fertility ($P < 0.05$). However, a weak positive correlation was found between the quality of informed consent and education ($P < 0.05$). Given that all participants in this study were Shia, no correlation can be found between the quality score of patients' informed consent to infertility treatment centers and religion. Due to the imbalance between the groups of first marriage (167 people (97.1%)) and second marriage (5 people (2.9%)), there can't be found any relationship between this variable and the quality of

The total quality score of informed consent of patients referred to infertility treatment centers is $6/457 \pm 21/16$ out of 44 points, which indicates its average quality.

informed consent of patients referred to the infertility centers.

Table 4. consenters' opinions about the relationship between physician and patient in the process of obtaining consent in patients referred to infertility centers in Rasht in 1398.

Questions	Yes	To some extent	No	I Don't Remember	No Answer	Total
Trust in the doctor	152(88.4)	19(11)	1(0.6)	-	-	172
Enough time to think and ask questions	74(43)	70(40.7)	28(16.3)	-	-	172
Possibility to contact the doctor	39(22.7)	38(22.1)	95(55.2)	-	-	172
Get complete answers to questions	81(47.1)	65(37.8)	26(15.1)	-	-	172
enough time for presenting the information	79(45.9)	63(36.6)	30(17.4)	-	-	172
Understandable physician description	125(72.7)	40(23.3)	6(3.5)	-	1(0.6)	172
Simplicity of the doctor's description	127(73.8)	39(22.7)	5(2.9)	-	1(0.6)	172
Total	677(56.2)	334(27.7)	191(15.9)	0	2(0.2)	1204

Discussion

The present study is a cross-sectional study that was performed on 172 infertile patients referred to Al-Zahra Infertility Treatment Center in the first 6 months of 1398. The samples were selected by simple random sampling and information was collected through a questionnaire through interviews. The results of the study showed that the dimension of "providing information" in the average state, the dimension of "ability to understand the consent form" in the excellent state, the dimension of "voluntary consent form" in the weak state, and the dimension of "doctor-patient relationship" in the good state. Among the 22 questions of this questionnaire, the best situation in terms of the quality of obtaining consent was related to the patient's trust and confidence in the doctor, and the lowest status was related to the patients' awareness of other treatment methods and their advantages and disadvantages.

In this study, 43.9% of people believed that the information provided was insufficient. In fact, most patients were satisfied with the explanations provided about the cause of infertility, infertility treatment method, and also the cost of their treatment, but they mentioned the lack of sufficient explanation about the jurisprudential and legal aspects, benefits and complications of treatment, the reason for choosing treatment, and they have not received other treatment options, which is consistent with the findings of

Meysami (14) and Badsar (10). In contrast to the present study, Howlader's study showed that most patients are aware of the complications of surgery and even the possibility of death (15). However, in another study in Italy, 44.6% of patients had insufficient information (16).

As mentioned, one of the weakest topics studied in this study is to provide information about the advantages and disadvantages of treatment methods, which has the same result as the study of Butrle (17), Ne'matollahi (18), Ajorpaz (11), and Sheikh Taheri (19).

The present study showed that most of the consenters for receiving infertility treatment (84.3%) considered the consent form to be understandable, which is contrary to the results of Sheikh Taheri's research (19), but consistent with Joff's study in the United States that 86% of patients considered the consent form to be comprehensible (20).

Findings of this study showed that most of them do not consider their choice of treatment voluntary (85.2%). In other words, like the findings of Sheikh Taheri's study (19), and Muzur, patients do not receive sufficient information about available treatments and have no involvement in treatment decisions. However, 80% of patients are willing to participate in decision-making for their treatment (21).

The voluntary dimension in the present study was

examined to obtain information about other treatment options. Volunteering can be undermined by inadequate understanding, incompetence to make decisions or lack of sufficient and impartial information, patient respect for the physician, and pain or anxiety. Avoidance of coercion, temptation, and deception are also among the pillars of voluntariness (22-26) which have not been studied in this study. Also, this study was performed only on people who were referred to the centers due to infertility, and as a result, the negative response of patients in the voluntary section may be due to the lack of alternative treatment for them in some cases.

56.2% of people referred to infertility centers were satisfied with the doctor's relationship with them. In the study of Ajorpaz et al., 64.5% of patients were satisfied with the relationship with the physician (11), which is consistent with this study. In this study, most patients found the physician's explanations understandable and the time to present information was sufficient, which was observed in the study of Yaghmaei et al. in 67.3% of patients. (27).

Also, 43% of the people considered the time given to think and ask questions to the doctor sufficient. Mckeague's study also demonstrated the importance of making it possible for patients to ask questions (28). As mentioned earlier; Among the 22 questions of the questionnaire used in this study, the best situation in terms of the quality of obtaining consent was related to the patient's trust and confidence in the physician (88.4%), which is consistent with the study of Ne'matollahi (18). However, most of the participants in this study (55.2%) reported the impossibility of contacting a doctor, which was unlike Sheikh Taheri's study (19).

One of the limitations of this study was the lack of cooperation of private centers in accessing patients and their information. Therefore, this study was performed only on those who referred to Al-Zahra Infertility Center, while by examining the quality of the satisfaction of those who referred to a private center, it would be possible to examine the difference in the quality of satisfaction obtained in these two centers.

Another limitation of this study that makes it difficult for patients to provide information and understanding

is the passage of time. the time between our contact with patients and the time of their referral to the infertility center to receive services is a few months, and this issue raises the possibility of forgetting the information given to the patient.

In this study, age, waiting time for fertility, religion, and multiple marriages were not associated with the quality of informed consent in this study, but a weak positive correlation was found between education level and the quality of informed consent, which is consistent with Minis studies (29), Faghanipour (30), Barzegar (13) and also Badsar (10).

Conclusion

In this study, the dimensions of "comprehensibility of consent form", "physician-patient relationship" and "providing information to the patient" are in the best condition, respectively, and "voluntary consent form" is the weakest dimension in the process of obtaining informed consent. So that the patient's knowledge of "benefits and side effects of other available treatments" as the biggest weakness and "patient trust in the doctor", as a strong point in the process of obtaining informed consent was obtained. Due to the significant relationship between the level of education and the quality of informed consent, it is suggested that the consent form be adjusted based on the level of literacy of patients. In this study, many people expressed the impossibility of contacting the doctor to resolve the ambiguity and ask their questions remotely (55.2%), which seems to have a significant effect on patients' trust in the doctor, so It is suggested that in future studies, the effect of patients' contact with physicians on the quality of informed consent should be investigated. In general, the quality of informed consent obtained in patients referred to infertility treatment centers in Rasht in 1398, has been reported as average.

Author contributions

SBMK, AM and ShD collected the data and wrote the paper. KD revised and finalized the article. All members of this article read the manuscript carefully and acknowledged it.

Acknowledgments

The present study is the result of a MD Degree in general medicine that was approved by the Research Council of the Vice Chancellor for Research and Technology of Guilan University of Medical Sciences on 2019 with the code IR.GUMS.REC.1398.176 This project has been done with the financial support of this center, and therefore the researchers consider it necessary to express their gratitude to the esteemed deputy.

Conflict of interest

The authors declare that they have no conflicts of interest.

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