

# The effects of the informed consent given for cesarean section on anxiety and knowledge

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## Summary

**Purpose:** To determine the effects of information given before cesarean section on women's anxiety levels and their knowledge about informed consent regarding it. **Materials and Methods:** Sixty women who elected to undergo cesarean section were included in the study. The data were collected using the pregnancy-related clinical information form, informed consent form, cesarean information form, and State and Trait Anxiety Inventory. Kruskal-Wallis test, Mann-Whitney U test, chi-square test and Pearson correlation were used as statistical methods. **Results:** The women's knowledge scores before and after they were informed about cesarean section were  $14.8 \pm 5.5$  and  $29.8 \pm 2.6$ , respectively ( $p < 0.05$ ). Their state anxiety scores before and after they were informed about cesarean section were  $28.4 \pm 6.6$  and  $28.0 \pm 5.9$ , respectively ( $p > 0.05$ ). **Conclusion:** It was determined that the participants' pre-training knowledge scores about cesarean section increased significantly after they were informed, and that their state and trait anxiety scores decreased very little after they were informed.

**Key words:** Applied and professional ethics; Clinical ethics; Health personnel; Informed consent; Obstetrics and gynaecology.

## Introduction

Cesarean section has become a common operation in developed and developing countries [1, 2]. The rate of cesarean delivery in the world in the last 15 years has steadily increased from five percent to over 20% [3, 4].

According to the Turkey Demographic and Health Survey (TDHS-2008) report [5], 36.7% of the babies born within the five years preceding the survey were delivered by caesarean section. Cesarean section rates in this country are a lot higher than 15% recommended by the World Health Organization (WHO) in the scope of "Health for All in 2000" [1, 6].

It has been reported that maternal morbidity and mortality rates related to cesarean delivery are four to seven times more than those related to normal delivery [1]. In this context, it is extremely important for a woman to obtain sufficient information about the complications and risks mentioned above and to choose the most appropriate one for her in the process of receiving the informed consent [7]. Informed consent is the conscious, voluntary appreciation and understanding of the information under no external pressure by a patient with adequate decision-making capacity after he/she is informed about the diagnosis and treatment methods he/she is to undergo and alternatives of these methods and the possible risks and benefits of all these methods [8, 9].

In many countries, a patient's right to be informed about his/her consent has been secured under special legal regulations of the countries [8, 9]. In Turkey, conditions regarding the limits of the information to be provided and the patient's appreciation are not clear.

While patients' consent is obtained, some difficulties are experienced due to cultural differences, the limits of the information to be provided for the patient, concern not to bother the patient, the patient's education level, decision-making ability, and anxiety [10]. Therefore, since the birth event is a phenomenon causing anxiety for women, it is gaining importance that the woman should give her consent after having really understood what it is. The procedure through which informed consent is received from patients is quite a new practice for many patients in this country. The majority of patients do not have sufficient information regarding the importance and contents of an informed consent.

Although there are a limited number of studies conducted on to what extent informed consent is understood by patients, the present authors have not been able to access any local study investigating whether the information provided is likely to achieve its goal. In the international literature too, the number of the studies conducted on the retention of information by patients after they are informed and then their informed consent is obtained is very few. In a number of studies too, it has been stated that women are not provided with clear enough information nor can they understand the information provided for them [11, 12].

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The purpose of this study was to determine the effects of informed consent given before cesarean section on women's anxiety levels and their knowledge about informed consent regarding cesarean.

The study is original since it determines the relationship between anxiety and informed consent which is obtained when a woman who is planned to have vaginal delivery throughout her pregnancy but decided to have cesarean section in 24 hours after being administered to the hospital. Obtaining the informed consent in a short time in the course of cesarean delivery can cause the patient to give the informed consent without being aware of the importance of it. On the other hand, the patient's anxiety can affect her understanding as well. Therefore, clarification of the situation is of importance.

## Materials and Methods

### Patients

Written informed consent was obtained from each subject, and the study protocol was approved by the Human Ethical Committee of the university (Record No: 2010-03/16). The study was performed in accordance with the principles of the Helsinki Declaration. The patients were told that it was entirely their own decision whether or not to participate in the study, that the data obtained would only be used within the scope of the study, and that the confidentiality of all personal information would be strictly protected.

The research is an experimental one. A preliminary study was performed on 15 women to confirm the reliability of the questionnaire in the light of the literature. Those not wanting to participate in the study, diagnosed with emergency caesarean section, in the active phase of stage 1 of delivery, or having a mental or systemic disease preventing them from answering the questions, and having received information about cesarean section, were excluded.

Patients who presented to the Maternity Ward of Cumhuriyet University Hospital and were decided to have cesarean section comprised the population of the study. With the values of  $\alpha = 0.01$ ,  $\beta = 0.10$ ,  $1 - \beta = 0.90$ , the test power was assessed as  $p = 0.89694$ , and it was decided to enroll 60 individuals in the study.

### Questionnaire

The following four forms were used to collect data:

- Socio-demographic characteristics and pregnancy-related clinical information form: this form includes questions about general socio-demographic characteristics and cesarean-pregnancy issues such as whether the patient has a chronic disease, whether she has developed any health problems during pregnancy, whether the pregnancy is voluntary, and how many cesarean sections she has undergone previously.
- Informed consent form: it is the form prepared by adding figures to the form previously prepared by the National Association of Obstetrics and Gynecology regarding caesarean section and used in clinics.
- Cesarean information form: this form was prepared within the framework of the informed consent after the literature was screened by the researchers [4, 13]. The form includes questions on how cesarean section is performed, its benefits, risks and complications, and alternative treatments.

- State and Trait Anxiety Inventory: it is designed to measure the patient's state and trait anxiety and is based on a four-point likert-scale. It includes 40 items: 20 of them measure state anxiety and the other 20 measure trait anxiety. The scale is in a paper-and-pencil format [14].

Since each scale includes 20 statements, the total score obtained from each scale ranges between 20 and 80. Cronbach's alpha of the inventory was determined to range between 83 and 92 for the state anxiety scale, and between 86 and 92 for the trait anxiety scale. The Anxiety Inventory was developed by Spielberg *et al.* in 1970. It was adapted into Turkish by Oner and Le Compte in 1977 [14]. In the present study, alpha coefficient was found to be 0.7091 for the State Anxiety Inventory and 0.6610 for the Trait Anxiety Inventory.

State anxiety refers to an acute situational-driven episode of anxiety. Trait anxiety refers to a personality trait that is stable over time. In the literature, it has been emphasized that the State Trait Anxiety inventory was found to reflect the relationship between anxiety and what pregnant women suffered [15].

The study did not include a control group. Women's evaluations before they were informed were considered as the control. The data were collected between June and October 2010. In order to avoid bias, the questionnaires were filled in and collected not by the researchers but by specially trained pollsters through face-to-face interviews.

The pollsters first used the form questioning the woman's socio-demographic characteristics and knowledge about cesarean section and then the state-trait anxiety scale form. Then the researcher verbally gave the patient information about cesarean section included in the informed consent using visual material. After the patient was informed, the same pollster who had filled in the state-trait anxiety scale form filled in the forms including the woman's knowledge about cesarean section and anxiety status.

### Statistical analysis

In statistical evaluation, the paired t-test was used to compare the knowledge scores with the anxiety scores both of which were achieved by the woman before and after she was given information. The relationship between knowledge scores and anxiety scores obtained before and after informing was evaluated with Pearson correlation.

For the evaluation of cesarean information scores, each correct answer was scored one point and each wrong answer was scored zero, and then the total knowledge score was obtained. Statistical analyzes were based on the total score.

In addition, Kruskal-Wallis test, Mann-Whitney U test, chi-square test and frequency were used as statistical methods. Significance was determined as  $p < 0.05$ .

## Results

Table 1 presents the demographic and selected clinical data of the study population. Of the participants, 36 (60%) were in the 18-28 age group, 33 (55.0%) were primary school graduates, 55 (91.7%) were housewives, 33 (55.0%) had two or more cesarean sections.

The women's knowledge scores before and after they were informed about cesarean section were  $14.8 \pm 5.5$  and  $29.8 \pm 2.6$ , respectively. The knowledge score after they were informed was significantly higher than the

Table 1. — Demographic and selected clinical data of the study population.

Variables	Values (n = 60)
<i>Age (years)</i>	
18-28	36 (60%)
29-39	23 (38.3%)
≥ 40	1 (2%)
<i>Marital status (married)</i>	
<i>Education</i>	
Primary school	33 (55.0%)
Intermediate-high school	22 (36.7%)
University	5 (8.3%)
<i>Occupation</i>	
Housewife	55 (91.7%)
State officer	3 (5.0%)
Self-employed	2 (3.3%)
<i>Social insurance</i>	
No	4 (6.7%)
Yes	56 (93.4%)
<i>Presence of chronic illness</i>	
No	51 (85%)
Yes	9 (15%)
<i>Pregnancy intention</i>	
No	22 (36.7%)
Yes	38 (63.3%)
<i>Presence of obstetrical illness</i>	
No	40 (66.7%)
Yes	20 (33.3%)
<i>Experience of hospital stay</i>	
No	11 (18.3%)
Yes	49 (81.7%)
<i>Experience of surgery</i>	
No	24 (40.0%)
Yes	36 (60.0%)
<i>Number of cesarean sections</i>	
One	27 (45.0%)
Two or more	33 (55.0%)
<i>Being aware of the right to have the informed consent</i>	
No	55 (91.7%)
Yes	5 (8.3%)
<i>Total</i>	<i>60 (100.0%)</i>

knowledge score before they were informed ( $p < 0.05$ , Table 2).

The participants' state anxiety scores before and after they were informed about cesarean section were  $28.4 \pm 6.6$  and  $28.0 \pm 5.9$ , respectively. Their trait anxiety scores before and after they were informed about cesarean section were  $65.2 \pm 5.7$  and  $65.1 \pm 5.7$ , respectively. When the pre- and post- state and trait anxiety scores were compared, it was determined that the difference was statistically insignificant ( $p > 0.05$ , Table 2).

According to the results of correlation analysis of the knowledge scores and state-trait anxiety scores before and after informed consent (Table 3), there were negative correlations between ESIACS and ESSAIC ( $r = -0.09$ ,  $p = 0.478$ ) but they were not of statistical significance. There was a moderate, positive correlation between ESIBCS and ESIACS ( $r = 0.25$ ,  $p = 0.050$ ). There was a strong, positive cor-

Table 2. — The comparison between the knowledge scores and the state-trait anxiety scores of the study group before and after they were informed about cesarean section.

Variables	Before informed consent (n = 60)	After informed consent (n = 60)	Significance*
Evaluation score of information	$14.8 \pm 5.5$	$29.8 \pm 2.6$	0.000
Evaluation score of trait anxiety	$65.2 \pm 5.7$	$65.1 \pm 5.7$	0.668
Evaluation score of state anxiety	$28.4 \pm 6.6$	$28.0 \pm 5.9$	0.622

\* Paired t test was used.

Table 3. — The relationship (Pearson correlation) between the knowledge scores and state-trait anxiety scores before and after the participants were informed about cesarean section.

Variables	State and trait anxiety scores					
	ESIBCS	ESIACS	ESSABIC	ESSAIC	ESTABIC	ESTAIC
ESIBCS		$r = 0.25$ $p = 0.050$	$r = 0.24$ $p = 0.60$	$r = 0.21$ $p = 0.113$	$r = 0.10$ $p = 0.128$	$r = 0.18$ $p = 0.166$
ESIACS			$r = 0.21$ $p = 0.100$	$r = -0.09$ $p = 0.478$	$r = 0.12$ $p = 0.345$	$r = 0.88$ $p = 0.509$
ESSABIC				$r = 0.69$ $p = \mathbf{0.001}$	$r = 0.35$ $p = \mathbf{0.006}$	$r = 0.36$ $p = \mathbf{0.004}$
ESSAIC					$r = 0.44$ $p = \mathbf{0.001}$	$r = 0.46$ $p = \mathbf{0.001}$
ESTABIC						$r = 0.97$ $p = \mathbf{0.001}$

ESIBCS: Evaluation score of information before informed consent about cesarean section. ESIACS: Evaluation score of information after informed consent about cesarean section. ESSABIC: Evaluation score of state anxiety before informed consent. ESSAIC: Evaluation score of state anxiety after informed consent. ESTABIC: Evaluation score of trait anxiety before informed consent. ESTAIC: Evaluation score of trait anxiety after informed consent.

relation between ESSABIC and ESSAIC ( $r = 0.69$ ,  $p = 0.001$ ), ESTABIC and ESTAIC ( $r = 0.97$ ,  $p = 0.001$ ), the difference between them (ESIBCS and ESIACS) was statistically significant ( $p < 0.05$ ).

There was no significant difference between the socio-demographic and selected clinical data of the study population, and their pre- and post-cesarean knowledge scores and state and trait anxiety scores. Only the difference between the increase in the mean state anxiety scores of the participants with no chronic disease ( $-0.8 \pm 4.9$ ) and that of the participants with a chronic disease ( $2.6 \pm 3.6$ ) was considered to be significantly low ( $p < 0.05$ ).

The difference between the increase in the mean state anxiety scores achieved by the participants with elementary or higher education ( $-4.3 \pm 3.0$ ) and that achieved by the participants with lower than elementary education ( $0.3 \pm 4.8$ ) before and after they were provided information was considered significantly low ( $p < 0.05$ ).

## Discussion

It was determined that the participants' pre-training knowledge scores about cesarean section increased significantly after they were informed, and that their state and trait anxiety scores decreased very little after they were informed.

### *The effect of anxiety*

Of the studies investigating the association between informing and anxiety levels after informing, some found higher anxiety levels [16] whereas some found lower anxiety levels [17], but neither high levels nor low levels were statistically significant [18]. In the same study, it was indicated that there was no relationship between video-based informing and anxiety [18]. The very small decrease determined in anxiety scores of the participants before and after they were informed was considered statistically insignificant.

In several studies, it was stated that training programs reduced anxiety levels [17, 19], and that in patients who were informed preoperatively, both anxiety levels [19-21], but especially state-anxiety levels, were lower [20, 22]. On the other hand, in the literature, it has been reported that preoperative education provided about cesarean section reduces preoperative state anxiety levels to a very small extent [23]. In the present study too, anxiety levels decreased after informing, but it was not significant. This situation can be explained in such a way that the woman focuses informing process in order to get the information she needs, but that her anxiety is not significantly affected since uncertainty continues.

In a study of neurosurgical patients in which Amsterdam Preoperative Anxiety and Information Scale was used, a positive correlation was reported between the anxiety level and need for information [19]. In another study, it was reported that patients, especially female patients, were anxious during the preoperative period and that there was a weak correlation between their knowledge scores and anxiety levels [24], and these results were similar to the present findings.

In the literature, it is stated that informed consent can play an important role in women's decision-making process and in experiencing less anxiety [25]. In the present study too, it was found that, although statistically not significant, women's anxiety level after being informed was lower than that before being informed. The study on the use of decision aid by pregnant women, it was stated that their anxiety level decreased after informing, which supports the results of the present study [26].

In a study conducted on pregnant patients [27], no significant relationship was determined between anxiety and socio-demographic characteristics; however, in another study, a significant relationship was found between prenatal anxiety scores and socio-demographic and pregnancy history findings [28]. In an article entitled "comparative study of anxiety between informed and not-informed patients in preoperative period", it was stated that there was no significant relationship between socio-demographic data and the level of anxiety [21]. In another study, it was reported that participants' education level did not affect their state anxiety levels [22].

In the present study, no significant correlation was statistically determined between socio-demographic and se-

lected clinical characteristics and their knowledge scores and anxiety scores. However, the increase in the mean state anxiety scores of those with primary and higher education was significantly lower. As the education level increases, the anxiety level decreases, which is due to the fact that education has a positive contribution to the ability to understand and interpret the information given. The reason why those with chronic diseases had higher anxiety scores might be due to their concerns that their chronic disease might put their health at risk and lead to an uncertainty about their health.

### *Information scores*

In a study in which the participants were informed with audio-visual interventions, it was stated that there was no increase in their knowledge/understanding level. However, several other studies show that information provided through audio-visual interventions is long-lasting. Although, the intervention may also have small positive effects on the quality of information disclosed, and may increase willingness to participate in the short term, it is argued that this evidence is weak [29].

In a study aiming at developing and pre-testing a decision board to facilitate informed choice about delivery approach in uncomplicated pregnancy, it was stated that there was an increase in women's knowledge scores, which is consistent with the present study results [30].

## **Conclusion**

In decision-making, submitting sufficient information, ensuring reasonable involvement, and having the individual understand the information are important components of the informed consent. According to the results of the present study, informed consent increases pregnant women's knowledge, and, although not significantly, decreases their anxiety level. As a result, it can be said that informed consent does not affect anxiety levels of women to undergo cesarean section, but increases their knowledge regarding it.

### *Limitations of the study and recommendations*

The time between providing information for the patient and anxiety controls was short due to cesarean section and this may have influenced the results. The study can be repeated by including patients from different cultures and planning different periods between anxiety controls and providing information.

The study is expected to contribute to the literature since it draws attention to the fact that how appropriate criteria and strategies can be established when the informed consent is obtained from patients in case the time is limited. It may be a guide for the evaluation and revision of legal regulations regarding the informed consent at the national level.



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