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The Quality of Obtaining Informed Consent for Cesarean Section in Public Hospitals of Iran

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Informed consent, Cesarean section, Patient rights

ABSTRACT

Introduction: About 50%-65% of births in Iran occur by Cesarean Section (CS). Informed consent (IC) is one of the most important ethical, legal, and professional requirements of a surgical procedure.

Objective: This study aimed to assess the quality of obtaining surgical IC from women underwent CS in public hospitals of Iran.

Materials and Methods: In this analytical study with cross-sectional design, 300 postpartum women who had CS referred to two public hospitals in Rasht, Iran were participated through stratified random sampling method in 2016. Data were collected using a two-part researcher-made questionnaire. Collected data were analyzed by using descriptive statistics, Kruskal-Wallis test, Mann-Whitney U test, and Spearman's correlation test.

Results: The mean age of participants was 29.84±5.9 years. The majority of them (45.3%) had education lower than high school. The overall mean score for the quality of obtained IC was 62.23±23.38, out of 150 points. Regarding its dimensions, quality of acquiring IC form (20.21±7.12, out of 40 points), provision of CS-related information (15.67±11.10, out of 45 points), voluntariness (7.53±6.95, out of 25), and the physician-patient relationship (18.81±8.87, out of 40 points) were perceived poor. Women's educational level had a significant correlation with the IC quality dimensions of voluntariness (P=0.0001) and physician-patient relationship (P=0.043). The number of deliveries (P=0.008), live births (P=0.031), and stillbirth (P=0.0001) had a significant correlation with acquiring the IC form. The voluntariness was significantly associated with the number of live births (P=0.023) and stillbirth (P=0.001). The physician-patient relationship dimension was significantly associated with the number of pregnancies (P=0.023) and abortions (P=0.0001). The overall quality of obtained IC was significantly correlated with the women' age (r=0.162, P= 0.005).

Conclusion: Most of women in Iran are not informed enough about the CS and its consequences. Health care providers should pay more attention to the women's characteristics when obtaining IC for the CS. We recommend essential changes in the process of obtaining surgical IC for the CS in public hospitals of Iran. Obtaining IC during pregnancy may reduce unnecessary CSs.

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Highlights

- There is a poor quality of obtaining IC for the cesarean section in public hospitals of Iran.
- Women's age and education are associated with the quality of obtaining surgical IC.
- High quality IC may reduce unnecessary cesarean sections.

Plain Language Summary

This study aimed to determine the status of obtaining informed consent for the cesarean section in public hospitals of Iran. It is crucial that every patient be aware of the advantages, disadvantages and alternative options before surgery. The results showed a poor quality of obtaining informed consent for the cesarean section in public hospitals. The results also showed that the quality of obtaining informed consent was related to the women's age and education. The results suggest that physicians and health care providers should give proper and adequate information to the women about the cesarean section to help them make the right decision and reduce the rate of this surgery in Iran

Introduction

Cesarean Section (CS) is a common obstetric surgery in the world [1]. It is a life-saving procedure when complications arise during pregnancy. Despite its advantages in emergencies, it may lead to perinatal risks and maternal implications as well as long-term consequences which are still under investigation [2-4]. The sophistication of the most surgical procedures including CS makes their potential risks and benefits unclear for patients. This ambiguity can create a dilemma for patients during the process of deciding on the type of delivery. Thus, the candidates for surgery need comprehensive information about their situation, the benefits and side effects of surgery, the procedure, and alternative options [5, 6].

Obtaining surgical Informed Consent (IC) from patients who undergo surgery is necessary in terms of ethical, legal, and care quality aspects [7]. According to a meta-analysis, the prevalence of CS in Iran is 48% [4]. This can help with providing the correct information about the advantages and disadvantages of CS and vaginal delivery [8]. In case of CS, surgical IC is considered as an ethical and legal requirement. It provides information about the potential benefits and risks of CS, alternative therapy, and anesthesia options [9, 10]. A recent meta-analysis reported that women with CS are at higher risk of maternal death and postpartum infection [2].

Many studies have reported that the lack of knowledge of vaginal delivery and CS is the major cause of increased CS rate compared to vaginal delivery [4, 11]. However, by increasing the knowledge of ethics and rights, health care providers should provide enough information to the patients so that they can make an informed decision.

This study aimed to investigate the current status of obtaining surgical IC in public hospitals in Iran and evaluate the relationship of patients' demographic and obstetric characteristics with the quality of obtaining surgical IC.

Materials and Methods

This is a descriptive-analytical study with a cross-sectional design conducted from February to April 2016. Study population consists of all women who had undergone CS in two selected public hospitals in Rasht, Iran. These two hospitals were chosen because one of them was an educational hospital mostly run by residents and the other one was a non-educational hospital run by obstetricians and covering patients with social security insurance.

A total of 592 CS had been performed in these two hospitals. The sample size was determined 300 using a formula by considering a 95% confidence interval, an acceptable error (d) of 3, and the estimated Standard Deviation (SD) of 0.25 for the quality of surgical IC obtained from a pilot study. Through stratified sampling method, two public hospitals were selected. The number of CS cases in each hospital was used as a criterion to determine the number of samples in each hospital. The number of CS cases in the educational hospital was nearly twice that in non-educational hospital.

The inclusion criteria consisted of being 18 years old and willingness to participate in this study. Those with

emergency CS were excluded because obtaining surgical IC for them was not legally allowed. Women with a history of mental disorders according to their medical records, or any other condition that can affect the patient's judgment were also excluded from the study. From 321 samples selected according to the CS records in postpartum wards using a random number table, 4 women were not interested in participating in the study and 17 (12 had age <18 years and 5 had emergency CS) were excluded from the study. Finally, samples were 200 from the educational hospital and 100 from the non-educational one.

The data collection tool was a researcher-made questionnaire consisting of two parts including general and main sections. The general section consists of 11 items surveying the patient's demographic characteristics (age, educational level, place of residence, and type of admission), obstetrics characteristics (number of pregnancies, deliveries, abortion, live birth, and stillbirth), the number of CS delivery and the reasons for the current and previous CS.

The first part of main section consisted of 7 items about conditions during obtaining IC and the comprehensibility of the IC form. These items include determining the person who signed the form, the person who signed the form as the witness, the person who obtained IC, the person who provided the patient with the CS-related information, the time that the CS-related information were presented to the patient, the patient's awareness of CS during signing, and the patient's position during signing. The main section had multi-choice questions but with no Likert-type scale for scoring. The second part of the main section consisted of 30 question and four subscales; 8 items were about the quality of acquiring surgical IC forms, 9 question were about the provision of related information, 5 question were about voluntariness, and the final 8 question were about the perceived quality of physician-patient relationship. These questions were rated on a Likert-type scale (0= Not at all, 1= Very low, 2= Low, 3= Moderate, 4= High, 5= Very high).

The total score ranged 0-150, where the higher scores indicated a better quality of obtaining surgical IC. In each subscale, the score <50 indicated poor quality, score 50-75 showed moderate quality, and score >75 represented adequate quality. The questionnaire was adapted from the studies by Joolaee et al. and Faghanipour et al. [12, 13]. Its content validity was determined according to the opinions of two obstetricians, two experts in ethics, and four midwifery faculty members and modifications were then made based on with their comments. For evaluating the internal consistency of the questionnaire using Cronbach's alpha coefficient, it was given to 20 study samples.

After completing the questionnaire by them, an overall alpha value of 0.8 was obtained which was acceptable. The Cronbach's alpha coefficient was reported 0.82 for the quality of acquiring surgical IC form, 0.84 for the provision of information, 0.78 for voluntariness and 0.76 for the perceived quality of physician-patient relationship.

Data were analyzed in SPSS v. 16 software. Data were described using descriptive statistics (frequency, mean and standard deviation) and, since Kolmogorov-Smirnov test results showed the data were not normally distributed, Kruskal-Wallis and Mann-Whitney U tests were used to compare the scores of surgical IC obtaining quality and its dimensions between women with different educational level, and Spearman's correlation test to investigate the correlation of surgical IC obtaining quality with age and obstetric characteristics of women.

Results

The mean age of participants was 29.84±5.9 years. The majority of them had lower levels of education, where 45.3% were with a level lower than the high school education. More than half of them (59.3%) were not the residents of Rasht city and were from other cities; 58.7% were admitted to the emergency department, and 60.6% had a previous experience of CS. The most frequent reason for the previous CS was "elective CS" (37.9%), while the most frequent reason for the current CS was "repeated CS" (58%) (Table 1). In 44.3% of women, the admission clerk was responsible for obtaining surgical IC from them, and 86% of the IC forms had been signed by the patients' husbands. All women were awareness (Table 2). The mean IC obtaining quality score was 62.23±23.38 out of 150. The quality of acquiring IC forms (20.21±7.12, out of 40), provision of CS-related information (15.67±11.10, out of 45), voluntariness (7.53±6.95, out of 25), and the physician–patient relationship (18.81±8.87, out of 40) were poor. Figure 1 compares the mean scores of overall IC obtaining quality and its dimensions categorized based on the quality levels.

The results indicated that 58% of those signed the IC forms had not read the form at all. Among those who had read the form (42%), 56.7% reported different degrees of incomprehensibility, and 49.7% reported difficult technical, medical, and legal terms. For 68% of patients, the quality of obtaining the IC for CS was poor. Among the patients' demographic characteristics, educational level was related to the amount of received in-

Table 1. Demographic and obstetric characteristics of participants

Variables		No. (%)
Education level	Elementary school	136 (45)
	High school diploma	116 (38.7)
	University degree	48 (16)
Place of residence	Rasht city	122 (40.7)
	Other cities	178 (59.3)
Type of admission	Elective	124 (41.3)
	Emergency	176 (58.7)
Number of CS	First time	118 (39.3)
	Several times	182 (60.6)
Reasons for previous CS *	Elective CS	69 (37.9)
	Cephalopelvic disproportion	30 (16.9)
	Lack of labor progress	28 (15.3)
	No idea	20 (10.9)
	Fetal complications	10 (5.4)
	Breech	9 (4.9)
	Placenta complications	8 (4.3)
	Having twin	4 (2.1)
	Having golden baby	4 (2.1)
Reasons for current CS	Repeat CS	174 (58)
	Elective CS	26 (8.7)
	No idea	26 (8.7)
	Fetal complications	24 (8)
	Having twin	22 (7.3)
	Cephalopelvic disproportion	10 (3.3)
	Placenta complications	8 (2.7)
	Breech	6 (2)
	Lack of labor progress	2 (0.7)
	Oligohydramnios	2 (0.7)

N=182

Table 2. Conditions related to obtaining IC

Variables		No. (%)
Who obtained IC?	Admission clerk	133 (44.3)
	Obstetrician	6 (2)
	Resident	6 (2)
	Nurse	8 (2.7)
	Midwife	38 (12.7)
	I don't know his/her position	109 (36.3)
Who provided you with CS-related information?	Admission clerk	10 (3.3)
	Obstetrician	77 (25.7)
	Resident	59 (19.7)
	Nurse	16 (5.3)
	Midwife	37 (12.3)
	I don't know his/her position	101 (33.7)
Who signed the form?	Husband	258 (86)
	Myself	42 (14)
Who signed the form as the witness?	Myself	258 (86)
	Husband/family member/relatives	42 (14)
What was your position during signing the form?	Sitting	148 (49.3)
	Standing	152 (50.7)
When you received the CS-related information?	During a visit to a physician	94 (31.3)
	During signing the form	40 (13.3)
	After hospitalization	166 (55.3)

Table 3. Mean Score of informed consent obtaining quality and its dimensions based on educational level

Dimensions	Mean±SD			Sig.*
	Elementary	High School Diploma	University Degree	
Quality of acquisition of IC form	20.65±7.53	19.64±6.00	20.35±8.35	0.604
Provision of CS-related information	16.85±11.67	14.74±10.91	14.54±9.71	0.325
Voluntariness	6.90±7.21	6.83±6.02	11.04±7.37	0.001
Physician–patient relationship	19.84±9.13	17.74±8.14	18.50±9.64	0.043
Total	64.24±25.39	58.95±21.41	64.44±21.49	0.071

*Mann-Whitney U test

Table 4. Correlation of surgical informed consent obtaining quality with age and obstetric characteristics

Dimensions		Age	Number				
			Pregnancies	Deliveries	Abortions	Live Births	Stillbirths
Quality of acquisition of IC form	r Sig.*	0.069 0.231	0.271 0.117	0.153 0.008	- 0.52 0.371	0.125 0.031	0.008 0.897
Provision of CS-related information	r Sig.*	0.037 0.518	0.083 0.152	0.089 0.123	-0.063 0.279	0.110 0.057	0.219 0.0001
Voluntariness	r Sig.*	-0.110 0.057	-0.094 0.102	- 0.096 0.096	-0.18 0.753	-0.131 0.023	-0.228 0.0001
Physician-patient relationship	r Sig.*	0.131 0.023	0.224 0.0001	0.098 0.090	0.145 0.012	0.022 0.709	0.112 0.054
Total	r Sig.*	0.162 0.005	0.105 0.069	0.060 0.229	0.056 0.338	0.005 0.930	- 0.057 0.324

* Spearman correlation test

formation, where the patients with higher educational level obtained more information. Kruskal-Wallis test results showed a significant difference between the three groups of educational level. Mann-Whitney U test after Bonferroni correction revealed a significant difference between groups with elementary and high school diploma in terms of voluntariness dimension (P=0.001), and a significant difference between groups with high school diploma and university degree in terms of physician-patient relationship (P=0.043) (Table 3). Spearman correlation test results showed the significant positive association of the number of deliveries (r=0.153, P=0.008) and live birth (r=0.125, P=0.031) with the quality of acquiring the IC forms. Moreover, age factor had a significant positive correlation (r=0.162, P=0.005) with the overall IC obtaining quality score (Table 4).

Discussion

The results of this study indicated a poor quality of obtaining surgical IC for the CS in selected hospitals. In most of the cases, the IC form was provided by admission clerk. Obtaining IC by non-professional staff can disrupt the process of shared decision-making and consequently may result in the interruption of patient's role in the treatment procedure. This result is consistent with the results of Joolaee et al [12]. For more than half of the women, the information was provided after hospitalization, most of which was about postpartum care and follow-up after discharge. About one-third of the women received information about the CS in an office-based setting, but they signed the IC form during admission. It has been suggested that the best time for obtaining surgical IC is when the patient is under less pressure [14].

Most of the women had not read the IC form during signing; half of them due to being in a hurry and other half due to fear and stress. About half of the women declared that they had no enough time to think and ask questions about the surgery. These results are in agreement with the findings of Joolaee [12]. On the other hand, a study in Italy reported that the majority of patients had adequate time to read the IC form before signing it [15]. Half of subjects in our study had read and

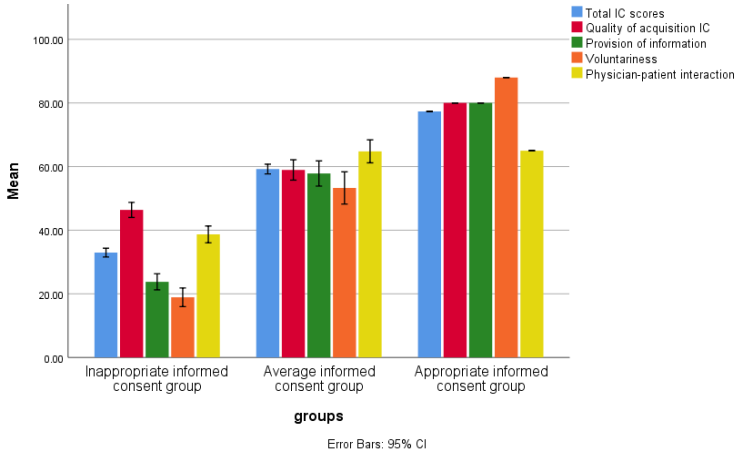

Figure 1. Comparing the mean scores of IC obtaining quality and its dimensions

signed the IC form in a standing position. This position can cause the signatory to feel uncomfortable. Moreover, about half of the women had admitted through the emergency department. Although all the women had decisional capacity, the IC form of the majority of them had been signed by their husbands. Agozzino et al. reported that most respondents signed the form themselves or it was signed by relatives or parents [15]. In Iran, a husband has the right to make medical decisions for his wife, especially for gynecological surgery and CS. Therefore, in most cases, the patient signs the form as a witness or do not sign it at all. A study in India reported that the IC forms are mostly signed by the relatives, not by the patients, and their relatives are informed before the surgery [9].

Many of women in our study reported a lack of understanding and half of them stated that the IC form contained unintelligible medical and legal terms. This is consistent with the results of Manta et al, where the content of IC was difficult to understand even for highly-educated patients [16], and is against the results of Agozzino et al., who reported that the majority of patients found the form understandable [15]. In current study, most of the women reported that they were informed about the CS, but their physician had not explained about its risks, benefits, anesthesia options, and the possibility of vaginal delivery. This is in accordance with the results of a recent study in Iran, indicating that the most of the patients had received insufficient information about IC in public hospitals [17].

A study on the adequacy of IC obtaining for CS in India showed that majority of the patients were adequately informed about the procedure and had adequate knowledge of it [18]. The results of a qualitative study in Iran revealed that specialists give general information about the surgery to the patients, and they are so cautious about informing the side effects and other treatment options [19]. More than half of the women in our study reported that they were not informed enough about the benefits and side effects of vaginal delivery and CS. This is in agreement with the results of Latika [18]. Tripathy et al. also reported that almost none of the patients were informed about their rights to refuse the procedure or they were not informed about the alternative procedure [20].

Half of the women in our study reported that they had appropriate relationship with their physician, and the physician replied to their questions and explained well about the surgery. This is in agreement with the results of Faghanipour [13]. More than half of the women in our study stated that they had no enough time to think after the physician's explanations. This is consistent with the results Joolaee [12], but aganist the results of Agozzino et al., who reported that the most of patients had enough time to read the IC form before surgery [15]. The results of current study showed that educated women opt more for voluntary CS. This is in agreement with the results of Shaker [17]. Furthermore, there was a positive relationship between patients' age and overall IC obtaining quality score. Hence, we can say that health care providers should pay more attention to the patients' characteristics when obtaining surgical IC.

Regarding the dimensions of surgical IC obtaining quality, women with higher number of pregnancies had higher scores in the quality of acquiring IC form, and those with a history of stillbirth had higher scores in the provision of CS-related information and lower score in voluntariness. It seems that women become more aware when they have an experience of pregnancy or stillbirth, but they may not opt for voluntary CS if they experience stillbirth.

Giving inadequate information to the women about the CS is may be one of the reasons for the uncontrolled growth of CS in Iran; therefore, obtaining surgical IC during pregnancy may reduce unnecessary CSs. This study was performed on patients undergoing CS in public hospitals in Rasht city. Although there were measures for obtaining surgical IC in these hospitals, they were not adequate. We suggest essential changes in the process of obtaining surgical IC for the CS in these hospitals. One of the limitations of this study was the impossibility of surveying the opinions of women referred to private hospitals. Further studies are recommended to investigate the quality of obtaining surgical IC in public and private hospitals in Iran.

Ethical Considerations

Compliance with ethical guidelines

This study approved by the Research Ethics Committee of Guilan University of Medical Sciences (Code: IR.GUMS.REC.2015.93). A written IC was obtained from all participants prior to study. They were assured of the confidentiality of their information, and that their responses would not have any impact on the process of their treatment.

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Authors' contributions

Conceptualization: Shadi Sabetghadam, Sedighe Rezaie Chamani; Writing original draft: Shadi Sabetghadam, Zahra Amirkhanzadeh Barandouzi; Data collection: Mona Rahnavardi, Yalda Donyaei Mobarrez; Data analysis: Shadi Sabetghadam, Sedigheh Sedigh Mobarakabadi; Editing & review: All authors.

Conflict of interest

The authors declared no conflict of interest.

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