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The potential beneficial effects of education and familiarity with cesarean section procedure and the operating room environment on promotion of anxiety and pain intensity: A randomized controlled clinical trial

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Abstract:

BACKGROUND: Anxiety before and pain intensity after cesarean section is among the factors that should be taken into consideration among the candidates for cesarean section. The present study aimed to investigate the effect of familiarity with cesarean section and the operating room environment on anxiety and pain intensity among the mothers undergoing cesarean section.

METHODS: This clinical trial was conducted on 80 women referred to the hospitals affiliated to Shiraz University of Medical Sciences for cesarean section in 2018. The participants were randomly divided into a control (n = 40) and an intervention group (n = 40). The intervention group took part in four educational sessions, while the control group received the hospital's routine care. The Beck Anxiety Inventory was completed by the two groups before and after the intervention. The McGill Pain Questionnaire was also filled out by the two groups in the ward after the cesarean section. After all, the data were entered into the SPSS software, version 21, and were analyzed using independent t-test and ANCOVA.

RESULTS: The results showed no significant difference between the two groups regarding the mean score of anxiety prior to the intervention. After the intervention, the mean score of anxiety was 7.98 ± 3.77 in the intervention group and 19.70 ± 6.45 in the control group, and the difference was statistically significant (P < 0.0001). Indeed, the mean intensity of pain was 43.98 ± 7.63 in the intervention group and 57.75 ± 10.69 in the control group after the intervention, and the difference was statistically significant (P < 0.017).

CONCLUSION: The patients' familiarity with cesarean section and the operating room environment caused a decline in the anxiety level prior to cesarean section as well as a decrease in the score of pain after the operation. Hence, midwives and nurses have to play effective roles in decreasing pregnant women's anxiety and pain through identification of strategies for empowering them and managing their worries.

Keywords:

Anxiety, cesarean section, familiarity operation room surgery, pain, training

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Introduction

esarean section refers to a type of surgical operation, which is carried out in the presence of the medical indications that make natural vaginal delivery dangerous for the mother or her infant.^[1] Based on the data obtained from 150 countries, the frequency of cesarean section was 18.6% around the world. [2] The prevalence of cesarean section was reported to be 32.2% in the US, 25% in Europe, [3] and almost 50% in China. [4] This measure was reported to vary from 26% to 60% in Iran. [4] Cesarean section is performed due to high birth weight, fetal distress, placenta previa, abnormal fetal position, and previous history of cesarean section.^[5] The maternal complications of this operation include pain (45.1%), headache (41%), reduced sexual satisfaction (29.71%), indigestion (29.1%), fever (16.3%), infection (13.5%), bleeding (8%), and incision site infection (5.36%). Its fetal complications also include transient tachypnea of the newborn, respiratory distress syndrome, hospitalization in the neonatal intensive care unit, and wounds caused by surgical blades.[6]

Ali et al. (2014) reported that the patients' anxiety level prior to operation varied from 20% to 80%, depending on the type of surgery. Indeed, the main reasons for preoperative anxiety included doubt about the success of the operation, fear from anesthesia, and fear from reduction of one's abilities.^[7] The effects of anxiety prior to birth include increased cortisol level, anti-inflammatory cytokines, and lower breastfeeding. Its impacts on infants also include preterm delivery and lower growth factor blood levels.[8] A previous study indicated that 30.9% of the mothers experienced anxiety at least once during their pregnancy, and 6.9% were anxious all through this period. [9] In the research performed by Kalliyath *et al*. in 2019, the incidence rate of preoperative anxiety was 60%-80%, which resulted from surgery, anesthesia, etc., In addition, the incidence rate of 1-year persistent pain was nearly 25% after cesarean section, which was higher compared to natural vaginal delivery.[10] In general, women experience high pain intensity within the first 24 h after cesarean section, which can continue up to 24–48 h after the operation.^[5]

Evidence has indicated that relaxation could be effective in reduction of pain. [11] Thus, pain relief is of particular importance after surgical operations. Pain resulting from the abdominal scar could interfere with the mother's placement in an appropriate position for breastfeeding and consequently disrupt effective breastfeeding. Moreover, pain can delay patient ambulation, which increases the incidence of thromboembolic disorders by increasing blood coagulability. Postoperative pain management can decrease patients' discomfort, lead to early ambulation, reduce the length of hospital stay, and enhance their satisfaction. Quick and sufficient pain

control after cesarean section also has a positive impact on early breastfeeding, which helps the contraction and shrinkage of the uterus after the operation. The findings of the study by Simonelli *et al.* demonstrated that massage therapy decreased the pain intensity, stress, and need for drugs after the operation. [12] Indeed, Kalliyath disclosed that mothers' training prior to cesarean section caused a decline in their anxiety and pain. [10] Chang also reported that patients' training before surgery resulted in better acceptance of the operation and reduced their anxiety in the intervention group. [13]

The previous studies were mainly focused on the prevalence, causes, and complications of cesarean section compared to natural vaginal delivery. Besides, limited interventional studies have been conducted on training the candidates for cesarean section. Therefore, the present study aims to investigate the effect of familiarity with cesarean section and the operating room environment on anxiety and pain intensity among the mothers undergoing cesarean section.

Methods

Study design

Sampling and education of mother began on September 15, 2019, and ended on November 12, 2019. It should be noted that due to the earlier identification of mothers in the maternal–child clinics, the sampling time has been reduced.

Study size

This clinical trial was conducted on 80 eligible pregnant women referred to Hafez and Zeinabiyeh hospitals affiliated to Shiraz University of Medical Sciences for cesarean section in 2018. Considering d=1, $1-\alpha=99\%$, $1-\beta=90\%$, and significance level = 0.05, an 80-subject sample size was estimated for the study. Three women needed emergency cesarean section, three mothers were replaced, and samples continued with 80 people in two groups of 40 [Figure 1].

Inclusion and exclusion criteria

The inclusion criteria of the study were elective cesarean section due to previous cesarean section or midwifery indications, gestational age of 34 weeks and above, parity >2, not suffering from anxiety and mental disorders and not consuming the related drugs, and not having the history of chronic pains. The exclusion criteria of the study were unwillingness to cooperate, incidence of complications during anesthesia or operation, preterm delivery, need for emergency cesarean section, and classical incision in the previous cesarean section.

Randomization

After gaining the approval of the Ethics Committee, sampling was started. In doing so, the eligible pregnant

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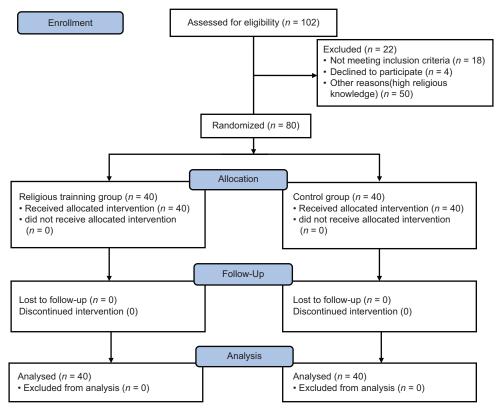


Figure 1: CONSORT flow diagram of participants

women referred to the gynecology and obstetrics clinics of Hafez and Zeinabiyeh hospitals for selective cesarean section were selected. The participants were then allocated to the intervention or the control group via permuted block randomization using 20 blocks with block size of 4.

The Beck Anxiety Inventory (BAI) was used to measure the participants' anxiety, and the McGill Pain Questionnaire was employed to assess their pain. BAI was developed by Beck et al. (1988) to specifically evaluate individuals' intensity of clinical anxiety. [15] This inventory has been translated and psychometricized in Iran. Some studies have also been conducted on its psychometric properties. In the research by Kaviani Hossein, the validity of this inventory was found to be nearly 0.72 in the Iranian population. Indeed, the test-retest reliability of the inventory with a 1-month interval was 0.83 and its Cronbach's alpha coefficient was 0.92.[16] BAI included 21 items responded through a four-point scale ranging from 0 to 3. Thus, the total score of the inventory could range from 0 to 63. It should be noted that each item of the inventory described one of the main symptoms of anxiety, i.e., mental, physical, and fear.

The McGill Pain Questionnaire is one of the dominant instruments used for the measurement of pain. This questionnaire contained 20 items, which aimed to assess individuals' perceptions of various dimensions of pain, i.e., sensory perception of pain, emotional perception of

pain, perception of pain evaluation, and different pains. The reliability and validity of the questionnaire were explored by Dorkin *et al.* in 2009. Accordingly, Cronbach's alpha coefficients were found to be 0.87, 0.87, 0.83, and 0.86, respectively. Moreover, Khosravi *et al.* performed a research in 2012 and reported the Cronbach's alpha coefficient of 0.85 for the entire questionnaire and 0.80 for its four components. In the present study, the modified form of the McGill Pain Questionnaire was employed. Indeed, the Cronbach's alpha coefficient reported by Khosravi was considered as the basis for this study.

Intervention

At first, the mothers were informed about the study objectives and were reassured about the confidentiality of their data. Then, they were required to sign written informed consent forms for taking part in the research and fill out the demographic information form. Afterward, the two groups were asked to complete BAI. The intervention group took part in four 45-min training sessions, while the control group received the hospital's routine care. The two groups were requested to complete BAI on the day of operation. The McGill Pain Questionnaire was also completed by the two groups in the ward after the operation [Table 1].

Statistical analysis

Descriptive statistics, mean, standard deviation, maximum, minimum, and column charts were used.

One-sample Kolmogorov–Smirnov test was also employed to determine the normal distribution of the data. In addition, Levene test that is one of the assumptions of ANCOVA was used to assess the equality of variances. ANCOVA was used to compare the means, and independent *t*-test was used to compare the two study groups. It should be noted that normal distribution of the data, convergence of regression slopes, and homogeneity of variances were determined in order to carry out ANCOVA. SPSS software, version 16 (IBM Company Armonk, NY, USA), was used for statistical analysis. In all tests, the significance level of 0.05 was considered.

Ethical considerations

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences in 2018 (proposal no. 18506, ethics code: IR.SUMS.REC.1398.300). It was also registered in the Iranian Registry of Clinical Trials (IRCT code: 20130710013940N6). The participants were informed about the study objectives and their written informed consent was obtained. They were also reassured that their participation in the study was completely voluntary and that they could withdraw from the study at any stage.

Results

The mean age of the participants was 27.4 ± 4.78 years in the control group and 27.92 ± 5.05 years in the intervention group. The mean gestational age

was 36.3 ± 1.26 weeks in the control group and 37.17 ± 1.1 weeks in the intervention group [Table 2]. In addition, 21 participants (34.4%) were experiencing their second pregnancy, while 59 ones (65.6%) had a history of more than two pregnancies. Besides, 90.2% of the participants reported their pregnancy to be planned. Furthermore, 35 participants (43.2%) had the history of a previous cesarean section. Finally, the majority of the participants were homemakers. The results of Chi-square test revealed no significant difference between the two groups with respect to age, education level, and occupation (P > 0.05). The results of Mann–Whitney test also showed no significant difference between the two groups regarding the number of miscarriages and pregnancies (P > 0.05). However, the number of cesarean sections was significantly higher in the control group compared to the intervention group (P < 0.05) [Table 3].

The results of ANCOVA indicated no significant difference between the two groups concerning the anxiety level prior to cesarean section (P > 0.05). However, the mean score of anxiety was significantly lower in the intervention group in comparison to the control group after the intervention (P = 0.0001) [Tables 4 and 5].

The results of independent t-test showed that the mean intensity of pain was significantly lower in the intervention group compared to the control group (P < 0.001) [Tables 6 and 7].

Table 1: Timing and objectives of the training sessions

Session	Title	Activities
First	Familiarity with the operating room environment and patient registration	Presenting pictures from the operating room environment, explaining about patient registration in the operating room and questions asked at entrance
Second	Familiarity with anesthesia and recovery techniques	Explaining about the conditions that may occur during anesthesia and uncommon conditions that should be reported by the patients, how patients are checked in the recovery room, length of stay in the recovery room, and issues checked in this unit
Third	Familiarity with the process of cesarean section	Explaining the operation simply, reasons for prepping and draping, issues and sounds existing during the operation, and how the infant is checked and transferred to the ward
Fourth	Wound care, prevention of infection and complications after anesthesia	Explaining about how to clean and dry the wound, medications consumption, and ways to reduce postoperative headache and pain

Table 2: Demographic information survey of two groups

Group	Age			Education				Job		
	20-25	26-30	31-35	36-40	Illiterate	Under Diploma	Diploma	Graduate and higher	Homemaker	Employed
Intervention, <i>n</i> (percentage in group)	15 (37.5)	11 (27.5)	10 (25.0)	4 (10.0)	13 (32.5)	7 (17.5)	11 (27.5)	9 (22.5)	31 (77.5)	9 (22.5)
Total percent	18.8	13.8	12.5	5.0	16.3	8.8	13.8	11.3	38.8	11.3
Control-n (percentage in group)	13 (32.5)	16 (40.0)	7 (17.5)	4 (10.0)	10 (25.0)	5 (12.5)	17 (42.5)	8 (20.0)	27 (67.5)	13 (32.5)
Total percent	16.3	20.0	8.8	5.0	12.5	6.3	21.3	10.0	33.8	16.3
Statistics	1.598		2.069			1.003				
P*	0.669		0.558			0.453				

*Chi-square test

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Table 3: Evaluation of difference between the two groups regarding three variables of abortion, pregnancy, and cesarean using Mann-Whitney test

Group	Quantity	Average rating	Average	SD	Test statistics	P
Abortion						
Intervention	5	4.30	2.4000	1.14018	-0.872	0.383
Control	4	5.88	3.2500	1.70783		
Total	9					
Pregnancy						
Intervention	40	40.09	2.8500	1.12204	-0.172	0.864
Control	40	40.91	2.8250	0.95776		
Total	80					
Cesarean						
Intervention	40	35.96	2.2750	0.67889	-2.031	0.042
Control	40	45.04	2.6000	0.77790		
Total	80					

SD=Standard deviation

Table 4: Anxiety score before and after the intervention in control and experimental groups

Anxiety	Quantity	Minimum-maximum	Average	SD
Experiment				
Pretest	40	4-29	16.25	6.98
Posttest	40	2-20	7.98	3.77
Control				
Pretest	40	2-30	12.55	5.71
Posttest	40	7-30	19.70	6.45

SD=Standard deviation

Discussion

The findings of the current study demonstrated that making the cesarean section candidates familiar with the operation and the operating room environment caused a decline in their anxiety and pain intensity. High anxiety levels might lead to negative outcomes in the candidates for cesarean section, including higher consumption of analgesics, higher heartbeat, lower immune response, and wound infection. Indeed, most anti-anxiety medications pass through the placenta and exert negative impacts on the fetus. Hence, nonpharmacological interventions for reduction of pregnant women's anxiety are of particular importance.[19] The present study results revealed that the mean score of anxiety was significantly lower in the intervention group compared to the control group, which represents the effectiveness of patients' training prior to the operation. In the same vein, Kalliyath *et al.* (2019) disclosed that training the intervention group mothers regarding the type of anesthesia was effective in reducing their anxiety level.[10] Chuang et al. also reported that training caused a decline in the patients' preoperative anxiety.[13] It should be noted that limited studies have been done in this field and no contradictory results were found.

The present study results indicated a change in the intervention group's anxiety level after the intervention compared to the baseline. Evidence has demonstrated

that placental function might change in case of maternal anxiety, which might control the exposure of the fetus' brain to such hormones as cortisol that could affect the growth of the brain. [20] On the other hand, stress and anxiety during the pregnancy period could increase the risk of undesirable complications, such as preterm delivery.[21] A study also reported that maternal anxiety was positively associated with low birth weight and preterm birth.[22] In general, pain and fear from the unknown can cause concerns in surgeries, and training the patients and informing them about the expected emotions may be helpful. [23] In the current study, the participants were trained about what to expect in the operating room. Preoperative anxiety might originate from fear, worries about the unknown, and having questions about the operating room, operation, and its outcomes. These issues were responded in the present study, eventually decreasing the mothers' anxiety.

The study findings showed that the intervention was significantly effective in reducing postoperative pain. Evidence has also revealed a relationship between anxiety before and pain after the cesarean section. Pain relief after the operation would lead to early ambulation, prevention of thromboembolic complications, improvement of outcomes, and promotion of mother's satisfaction. Kalliyath also reported that preoperative training was effective in decreasing the mothers' postoperative pain. Training could positively influence the individuals' behaviors and attitudes. Thus, preparing the mothers through reducing their anxiety and the subsequent complications could decrease their postoperative pain. [10] These results were in agreement with those of the present investigation.

Preoperative anxiety increases the risk of severe pain after cesarean section. One of the nonpharmacological approaches for reduction of postoperative pain is relaxation, which aims to decrease the anxiety and

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Table 5: Results of the analysis of covariance of anxiety to evaluate intervention in posttest

References	Sum of squares	Degrees of freedom	Average of squares	F statistics	Significance level	Impact rate
Pretest	835.061	1	835.061	48.045	0.0001	0.384
Group	3417.175	1	3417.175	196.607	0.0001	0.719
Error	1338.314	77	17.381			

Table 6: Descriptive information on maternal pain intensity in two control and experimental groups

<u> </u>				
Maternal pain	n	Minimum-maximum	Average	SD
Experiment	40	27-60	43.98	7.63
Control	40	38-75	7557.75	10.69

SD=Standard deviation

Table 7: Independent t-test for mother's pain severity in the control and experimental groups

F-statistic	Significance T-statis		Degrees of	Significance	Difference	CI 95%	
(Levin test)	level		freedom	level	between averages	Lower limit	Upper limit
5.952	0.017	6.633	70.5	0.0001	13.7750	9.63348	17.91652

CI=Confidence interval

tension associated with the body's physiological status.^[5] In this context, postoperative pain relief is of utmost importance among the patients. Other studies have shown that in addition to educational protocols, complementary medicine, including pressure medicine, compresses, and herbal remedies, is also effective in reducing pain and anxiety in women's problems. [25-33] The present study findings revealed a significant decrease in postoperative pain in the intervention group compared to the control group. In fact, the interventions and consultation services that aimed at reduction of the patients' psychological load prior to cesarean section resulted in better acceptance of the process of operation and the following period. In this study, the mothers were trained regarding the appropriate position after the operation, time and method of using suppository analgesics, deep breathing, and muscle relaxation, which enhanced their knowledge of pain control after the operation.

The previous studies were mainly focused on the causes and complications of cesarean section and other nonpharmacological methods for reduction of anxiety and pain associated with this operation. However, limited studies have been conducted on the impact of training among the candidates for cesarean section. One of the strong points of the present research was focusing on training the mothers and enhancing their knowledge level regarding the operation and the operating room environment as well as investigating anxiety and its impact on the mothers' postoperative pain intensity. Nonetheless, one of the study limitations was that primiparous women and those referred to private hospitals were not included. Although the intervention employed in this study could not replace pharmacological analgesics, it could provide a suitable complementary instrument. The strength of the plan is that, given that cesarean section rates are increasing in developed and developing countries, previous and ongoing training can possibly reduce the risk of cesarean delivery. The weaknesses of this study are the nonparticipation of nulliparous women and pregnant women referring to private hospitals.

Conclusion

Familiarizing the mothers with cesarean section and the operating room environment decreased their anxiety and pain. Considering the effectiveness of this method, it is recommended to be used for patients prior to surgical operations so as to decrease their anxiety and pain as well as the resultant postoperative complications. Moreover, in order to strengthen the mothers' mental capabilities, due attention should be paid to decreasing their worries during the pregnancy period so as to determine appropriate strategies for management of their worries and reduction of their anxiety and pain.

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Conflicts of interest

There are no conflicts of interest.

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