



Original Article

## Investigation of the pregnant women desire to choose the type of anesthesia during cesarean section in imam khomeini hospital, sari, iran, in 2017

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### Abstract

**Background:** Type of anesthesia during elective cesarean is very important and is chosen according to the decision of the specialist as well as the mother's desire. This study aimed to determine the rate and associated factors of choosing general or regional (spinal and epidural) anesthesia among pregnant women who underwent elective cesarean in hospitals of Northern Iran in 2017.

**Methods:** This descriptive-analytic study included the pregnant women referred to the hospitals in Sari with indications for both kinds of anesthesia. The reasons for choosing the type of anesthesia were asked and collected in a researcher-made checklist. The collected data were described and analyzed using SPSS software (version 24) through the Chi-square or Fisher's exact tests and Logistic regression. A p-value less than 0.05 was considered statistically significant.

**Results:** Out of 384 pregnant women who participated in the study, 60% and 40% of the cases chose general and regional anesthesia, respectively. Fear of spinal cord damage (64.3%) and fear of observing and hearing in the operation room (53.3%) were the most reasons for the rejection of the regional methods of anesthesia. However, the fear of not waking up (54.3%) and being interested in seeing the baby during childbirth (40.7%) were the main reasons for choosing spinal anesthesia. Most of the women who had experienced regional anesthesia selected this procedure in the current operation (53%), while general anesthesia was chosen by women without previous history of regional anesthesia (62%).

**Conclusion:** Although most of the pregnant women selected general anesthesia, the reasons for rejecting the spinal method were mainly non-scientific and could be managed with maternal education.

**Keywords:** Analgesia, Anesthesia Conduction, Cesarean Section, Patient Preference, Pregnant Women

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## Introduction

Cesarean as a surgical careful technique is associated with a decrease in the fetal complexities of the hazardous vaginal delivery. It is compulsory on the account of fetal asphyxia. However, the rate of perinatal inconveniences is higher after cesarean, compared to vaginal delivery. Aside from muscle relaxants, every single sedative medication can go through the placenta and influence the fetus. Hyperventilation, hypoxemia, and hypercapnia of the mother just as untreated hypertension have an effect on the neonate (1, 2). The type of anesthesia is selected according to the baseline reasons of the operation, degree of the emergency, and tendency of the anesthesiologist as well as the patient. None of these procedures are free of adverse complications, and the specialist has to select the most convenient method for the patient and surgeon with minimum risks, such as fetal depression (2).

General anesthesia is selected when the patient does not accept the regional anesthesia in the case of the contraindications of the regional anesthesia or time limitation during the emergency operations. Rapid induction, lower rates of hypotension and cardiovascular instability, as well as better airway control, are the main advantages of general anesthesia.

Around 40% of anesthesia-related maternal mortality is due to anoxia. Aspiration and difficult intubation are the main reasons for anoxia and hypoxia. Therefore, this procedure should be performed with caution, and it is necessary to develop preventive strategies in this regard (1-4).

During regional anesthesia, the patient is alert and able to enjoy watching her child birth. In addition, mother consciousness is an advantage for the anesthesiologist to prevent aspiration. The potential intubation injuries do not occur during regional anesthesia. Moreover, the depressive effects of the anesthetic drugs are omitted, and it is possible to provide high oxygen concentrations for the mother (1, 2, 5).

The choice for selecting the kind of anesthesia is made by the anesthesiologist and relies upon the clinical circumstance of mother and embryo

just as the crisis level of the task. In any case, in most elective circumstances, it also relies upon the mother's choice (6). In this way, pregnant ladies should be mindful of various sorts of anesthesia, as well as their advantages and drawbacks before the activity to have the option to select the best choice without impulse (7, 8). This study was conducted due to the cultural diversity of different regions of the country and the information gap in Mazandaran, Iran.

In a study conducted by Fassoulaki et al. in Greece, spinal anesthesia was chosen for cesarean by 80% of the women (9). On the other hand, 70% of the Nigerian women selected general anesthesia during cesarean (10). Moreover, 57.8% and 42.2% of the Iranian pregnant women referred to the hospitals in Tehran and Semnan, Iran, preferred spinal and general anesthesia, respectively (11). Generally, the desire for spinal anesthesia is getting increased worldwide because of the increasing rates of risks for general anesthesia. However, several studies have reported different rates based on various factors (9-11). Therefore, this study was conducted to determine the rate of different methods of anesthesia preferred by pregnant women for cesarean and the associated factors in Northern Iran.

## Materials and Methods

This cross-sectional study was carried out on pregnant women referred to Imam Khomeini Hospital, Sari, North of Iran, for cesarean in 2017. The required sample size was estimated at 384 women for detecting a prevalence of 57.8% (12), accuracy of 0.05, and 95% confidence level.

The pregnant women were recruited in the study if they met the inclusion criteria, such as eligibility for elective cesarean Class I&II, willingness to participate in the study, and no contraindication for both methods of anesthesia (regional and general). On the other hand, the women whose ASA Class was more than II, and those who were not willing to participate in the study and did not agree at least on one of the two anesthesia procedures were excluded from the study.

The study protocol was approved by the Ethics Committee of Mazandaran University of Medical Sciences, Sari, Iran (IR.mazums.Imam hospital. rec.1396.10200), and informed consent was obtained from the pregnant women. Afterward, interviews were conducted by trained interviewers before the operation. A relevant checklist was completed including variables, such as age, education level, occupational status, place of residence (urban/rural), history and type of anaesthesia, as well as the type of anesthesia preferred by the pregnant women in the current cesarean and reason for that. The evaluated factors affecting general anesthesia preference or regional anesthesia included fear of awareness during the operation, fear of spinal cord injury, fear of back pain, fear of paralysis, fear of lumbar puncture and fear of feeling pain during the operation, fear of non-waking up, fear of postoperative pain, alert during the child birth, and inability to breastfeeding.

All participants were informed of the research objectives and procedure, and they were also assured of the confidentiality of their information and the voluntary nature of the study without any influence on their delivery and operation.

The obtained data were analyzed in SPSS software (version 24) through descriptive statistics (mean $\pm$ SD) and inferential statistics (number and percent). Furthermore, the factors of interest were compared between groups using the Chi-square or Fisher's exact tests. Analytical statistics related to the role of factors affecting the patients' preferences in selecting anesthesia were used using parametric and non-parametric tests for quantitative and qualitative variables, respectively. In addition, logistic regression was employed to determine the role of variables. A p-value less than 0.05 was considered statistically significant.

## Results

In total, 384 pregnant women participated in this study with a mean age of 27.4 $\pm$ 5.6 years (age range: 18-45 years). Moreover, 260 (67.71%) mothers were living in urban areas, and the majority (34.38%) of them had diploma degree. Regarding

occupational status, 82.55% of the participants were housewives, and 57.03% of them had their first pregnancy. General anesthesia was chosen by 232 (60.42%) of the women, while 152 (39.58%) pregnant women selected spinal anesthesia.

Pregnant women who preferred general anesthesia reported factors, such as fear of hearing and seeing during the operation (53.3%), fear of spinal cord injury (64.3%), fear of back pain (49.6%), fear of paralysis (48.3%), fear of lumbar puncture (50.4%), and fear of feeling pain during the operation (29.1%) as reasons for choosing this anesthesia method.

Women selected regional anesthesia reported other reasons, such as being alert during childbirth (40.7%), fear of non-waking up (54.3%), fear of nausea/vomiting (40%), fear of postoperative pain (27.9%), fear of urinary retention (25.7%), fear of anorexia (20%), fear of headache (25.7%) and inability to breastfeeding (36.4%).

As can be observed in (Table 1), the women under the age of 25 years, and those from 31 to 35 years selected regional anesthesia more than the other method, compared to the women aged 25-30 and 36-40 ( $P=0.002$ ). This difference was between the age group of 25-35 years and 36 years or above, as well as those who aged under 25 years. The relationship between the other factors and type of anesthesia has been shown in (Table 1).

Furthermore, the tendency to anesthesia was significant among employed women and housewives ( $P=0.027$ ). Education level had an effect on the participants' fear of spinal anesthesia, and the participants with diploma degrees were more afraid of back pain. In addition, the cases with associate degrees were more afraid of observing the surgery and had a fear of lumbar puncture. The women with bachelor degrees were more afraid of spinal cord injury (Table 2). Variables, such as education level and occupational status affected participants' fear of spinal anesthesia. (Tables 2 and 3) show no relationship between age and reasons for selecting such a method among women who selected general anesthesia ( $P=0.429$ ).

A significant association was also observed

between these factors among women who preferred regional anesthesia ( $P=0.001$ ). Different factors related to selecting regional or general anesthesia have been illustrated in (Tables 2 and 3). In total,

55% of the participants between the ages of 36 and 40 were interested in being awake at the time their child was born, while 48.4% of the women under the age of 25 did not like to be awake (Table 3).

**Table 1.** Factors associated with the type of anesthesia among women who underwent cesarean

| Variables                     | General anesthesia<br>N (%) | Regional Anesthesia<br>N (%) | P-value |
|-------------------------------|-----------------------------|------------------------------|---------|
| Age group (year)              |                             |                              |         |
| <25                           | 16 (6.9)                    | 15 (9.9)                     | 0.002   |
| 25-30                         | 131 (56.5)                  | 71 (46.7)                    |         |
| 31-35                         | 30 (12.9)                   | 42 (27.6)                    |         |
| 36-40                         | 43 (18.5)                   | 16 (10.5)                    |         |
| >40                           | 12 (5.2)                    | 8 (5.3)                      |         |
| Place of residence            |                             |                              |         |
| Urban                         | 157 (67.7)                  | 103 (67.8)                   | 0.985   |
| Rural                         | 75 (32.3)                   | 49 (32.2)                    |         |
| Education level               |                             |                              |         |
| <Diploma                      | 59 (25.4)                   | 36 (23.7)                    | 0.828   |
| Diploma                       | 77 (33.2)                   | 55 (36.2)                    |         |
| Associate degree              | 19 (8.2)                    | 15 (9.9)                     |         |
| =>Bachelor degree             | 77 (33.2)                   | 49 (30.3)                    |         |
| Occupational status           |                             |                              |         |
| Housewife                     | 185 (79.7)                  | 132 (86.8)                   | 0.027   |
| Government job                | 32 (13.8)                   | 8 (5.3)                      |         |
| Non-government job            | 15 (6.5)                    | 12 (7.9)                     |         |
| History of spinal anesthesia  |                             |                              |         |
| Yes                           | 31 (13.4)                   | 35 (23)                      | 0.014   |
| No                            | 201 (86.6)                  | 117 (77)                     |         |
| History of general anesthesia |                             |                              |         |
| Yes                           | 143 (61.6)                  | 87 (57.2)                    | 0.386   |
| No                            | 89 (38.4)                   | 65 (42.8)                    |         |

**Table 2.** actors associated with selecting general anesthesia among pregnant women who underwent cesarean

| Variables                     | Fear of observing the operation (%) | Fear of spinal injury (%) | Fear of back pain (%) | Fear of paralysis (%) | Fear of lumbar puncture (%) | Fear of post-operative pain (%) | P-value |
|-------------------------------|-------------------------------------|---------------------------|-----------------------|-----------------------|-----------------------------|---------------------------------|---------|
| Age group (year)              | 18.8                                | 18.8                      | 12.5                  | 25                    | 12.5                        | 12.5                            | 0.429   |
| <25                           | 18.5                                | 24.3                      | 14.6                  | 15.1                  | 18.5                        | 9                               |         |
| 25-30                         | 21.4                                | 14.3                      | 23.8                  | 17.9                  | 13.1                        | 9.5                             |         |
| 31-35                         | 17.8                                | 20                        | 17.8                  | 14.8                  | 17.8                        | 11.8                            |         |
| 36-40                         | 8.3                                 | 25                        | 25                    | 16.7                  | 16.7                        | 8.3                             |         |
| >40                           |                                     |                           |                       |                       |                             |                                 |         |
| Place of residence            | 18.8                                | 24                        | 18.3                  | 13.8                  | 15.9                        | 9.3                             | 0.100   |
| Urban                         | 17.1                                | 18.7                      | 14.7                  | 20.1                  | 18.7                        | 10.7                            |         |
| Rural                         |                                     |                           |                       |                       |                             |                                 |         |
| Education level               |                                     |                           |                       |                       |                             |                                 | 0.001   |
| <Diploma                      | 21.3                                | 17.5                      | 13.1                  | 13.1                  | 24                          | 10.9                            |         |
| Diploma                       | 13.6                                | 18.9                      | 22.4                  | 17.8                  | 15.2                        | 12.1                            |         |
| Associate degree              | 24.6                                | 19.6                      | 6.6                   | 18                    | 24.6                        | 6.6                             |         |
| =>Bachelor degree             | 18.9                                | 29.7                      | 16                    | 17                    | 11.3                        | 7.1                             |         |
| Occupational status           |                                     |                           |                       |                       |                             |                                 | 0.006   |
| Housewife                     | 16.932                              | 21                        | 19.5                  | 15.4                  | 17.8                        | 9.4                             |         |
| Government job                | 17.2                                | 27.6                      | 13.8                  | 17.2                  | 13.8                        | 10.4                            |         |
| Non-government job            | 29.2                                | 18.5                      | 0                     | 23.1                  | 16.9                        | 12.3                            |         |
| History of spinal anesthesia  | 12.3                                | 19.7                      | 23.1                  | 20.3                  | 16.3                        | 5.6                             | 0.068   |
| Yes                           | 19.1                                | 21.1                      | 15.6                  | 15.7                  | 17.2                        | 11.2                            |         |
| No                            |                                     |                           |                       |                       |                             |                                 |         |
| History of general anesthesia | 18.6                                | 19.6                      | 17.1                  | 20.3                  | 16.3                        | 5.6                             | 0.079   |
| Yes                           | 16.9                                | 25.8                      | 16.2                  | 15.7                  | 17.2                        | 11.2                            |         |
| No                            |                                     |                           |                       |                       |                             |                                 |         |

**Table 3.** Factors associated with selecting regional anesthesia among pregnant women who underwent cesarean

| Variables                             | Being alert during childbirth (%) | Non-awaking up (%) | Vomiting/ Nausea (%) | Post-operative pain (%) | Urinary retention (%) | Anorexia (%) | Headache (%) | Inability to breastfeeding (%) | P-value |
|---------------------------------------|-----------------------------------|--------------------|----------------------|-------------------------|-----------------------|--------------|--------------|--------------------------------|---------|
| Age group (year)                      | 0                                 | 48.4               | 25.8                 | 12.9                    | 0                     | 0            | 0            | 12.9                           | * 0.01  |
| <25                                   | 19.4                              | 19.4               | 10.4                 | 9.7                     | 7.8                   | 4.5          | 10.4         | 17.4                           |         |
| 25-30                                 | 16.1                              | 12.6               | 16.9                 | 13.6                    | 10.1                  | 6.8          | 6.8          | 10.1                           |         |
| 31-35                                 | 45.4                              | 24.1               | 6.1                  | 0                       | 6.1                   | 6.1          | 6.1          | 6.1                            |         |
| 36-40                                 | 0                                 | 0                  | 20                   | 10                      | 20                    | 20           | 20           | 10                             |         |
| >40                                   |                                   |                    |                      |                         |                       |              |              |                                |         |
| Place of residence                    | 18.8                              | 24                 | 18.3                 | 13.8                    | 15.9                  | 9.3          | 11           | 15.4                           |         |
| Urban                                 | 17.1                              | 18.7               | 14.7                 | 20.1                    | 18.7                  | 10.7         | 6.4          | 9.6                            |         |
| Rural                                 |                                   |                    |                      |                         |                       |              |              |                                |         |
| Education level                       | 0                                 | 17.5               | 13.1                 | 13.1                    | 24                    | 10.9         | 12           | 8                              | *0.010  |
| <Diploma                              | 13.6                              | 18.9               | 22.4                 | 17.8                    | 15.2                  | 12.1         | 3.1          | 15.3                           |         |
| Diploma                               | 24.6                              | 19.6               | 6.6                  | 18                      | 24.6                  | 6.6          | 14.8         | 14.8                           |         |
| Associate degree<br>=>Bachelor degree | 18.9                              | 29.7               | 16                   | 17                      | 11.3                  | 7.1          | 13.2         | 15.7                           |         |
| Occupational status                   |                                   |                    |                      |                         |                       |              |              |                                | *0.001  |
| Housewife                             | 16.932                            | 21                 | 19.5                 | 15.4                    | 17.8                  | 9.4          | 9.4          | 12.7                           |         |
| Government job<br>Non government job  | 17.2<br>29.2                      | 27.6<br>18.5       | 13.8<br>0            | 17.2<br>23.1            | 13.8<br>16.9          | 10.4<br>12.3 | 0<br>25      | 16.7<br>25                     |         |
| History of spinal anesthesia          | 12.3                              | 19.7               | 23.1                 | 20.3                    | 16.3                  | 5.6          | 5.1          | 10.1                           | 0.063   |
| Yes                                   | 19.1                              | 21.1               | 15.6                 | 15.7                    | 17.2                  | 11.2         | 10.7         | 14.4                           |         |
| No                                    |                                   |                    |                      |                         |                       |              |              |                                |         |
| History of general anesthesia         | 18.6                              | 19.6               | 17.1                 | 20.3                    | 16.3                  | 5.6          | 14.1         | 10                             | 0.02    |
| Yes                                   | 16.9                              | 25.8               | 16.2                 | 15.7                    | 17.2                  | 11.2         | 4.4          | 17.2                           |         |
| No                                    |                                   |                    |                      |                         |                       |              |              |                                |         |

\*Fisher's exact test analysis

## Discussion

This study was conducted to investigate the degree of Iranian women's tendency for choosing general or spinal anesthesia during cesarean. These anesthetic techniques are the essential parts of the cesarean operation and are selected dependent on maternal and fetal circumstances (12). In many circumstances, especially in non-emergency and elective cases, decision-making is up to the mother's desire (6). In our study, 60% of the mothers preferred general anesthesia, while 40% of them decided to be spinally painless. Sadeghi et al. reported that half of the pregnant women in Tehran, the capital of Iran, selected general anesthesia, and 30% of them preferred the spinal method; however, 20% of the cases did not select any method for being painless (13). General anesthesia was the choice of all pregnant women attending hospitals for cesarean section in Torbate Heidarieh, Iran (14). However, another study conducted among pregnant women referring to health care centers in Tehran (capital of Iran), showed that only 39.9% of the cases tended to undergo general anesthesia (15). That was also the choice for women from some other countries, such as Nigeria, in which 70% of pregnant women selected the general method (10). On the other hand, Foruzeshfard et al. found that most pregnant women (58%) chose spinal anesthesia during their first delivery (11). Some other studies carried out in Greece (80% spinal method) and England (96% spinal method) reported different results, compared to those observed in the current study (9, 16).

This study showed that most women preferred general anesthesia due to the fear of spinal injury, observing and hearing the events in the operation room, and lumbar puncture. However, the fear of not waking up and also the tendency to be alert during the childbirth were the most reasons for choosing spinal anesthesia. These reasons were similar to those reported by Bukar who conducted a study on Nigerian women (10). The women's desire to watch their baby during delivery and fear of spinal injury were the most causes for choosing general and spinal anesthesia, respectively,

among pregnant women in Greece [9], which was consistent with the results of the present study. Although Foruzeshfard et al. (11) found similar factors for general method preference, spinal anesthesia was rejected by women mostly because of fear of back pain. It should be noted that this factor had less value among women who participated in the current study.

In the same line, Sadeghi et al. reported fear of not waking up as the main factor for rejecting general anesthesia which was similar to our results. However, most of their participants did not prefer the spinal method due to the fear of back pain (13). Other studies reported fear of back pain (17) and feeling the visual and audible events (18) as the most reasons for selecting general anesthesia or rejecting regional anesthesia. It is worth mentioning that interest to be alert during childbirth was one of the main reasons for choosing spinal anesthesia. It can be applied to encourage mothers to prefer this method of anesthesia during cesarean section. Some of the reasons reported by the pregnant women for rejecting spinal anesthesia during the current research were not scientific. It seems that the spinal technique conducted by needling the lumbar area has concerned pregnant women. In other words, general anesthesia has been chosen mostly due to the fear of lumbar puncture and not because of the advantages of the general method. In addition, general anesthesia is not satisfactory for many women and makes them anxious before operation. Maheshwari et al. in Pakistan found that the rate of anxiety was significantly higher among women selecting general anesthesia, compared to those selecting the spinal method (19). Therefore, an increase in the knowledge and attitude of women can lead to the reduction of fear of spinal techniques and increase their interest in this type of anesthesia before cesarean section.

In the current study, the history of general anesthesia was not in favor of selecting this method in the new operation; therefore, 40% of pregnant women who underwent general anesthesia during the last cesarean preferred to be painless by a spinal technique in the current operation. On the

other hand, women with previous experience of spinal anesthesia, compared to those without it, chose this method more significantly in the current cesarean operation, and the general method was selected mostly by those who had not experienced the spinal technique. This finding indicates the fact that being anesthetized by the spinal method during surgery will encourage women to prefer this type of anesthesia in the next operations while that is not the case for general anesthesia. In fact, direct experience of spinal anesthesia can be better than presenting each method to increase the knowledge and attitude of pregnant women toward selecting this method. Indeed, women with the experience of each type of anesthesia selected the same method in the next cesarean section (11).

Among women who preferred general anesthesia, there was no relationship between age and the reason for selecting this method, and these factors were the same for all age groups. Conversely, among women choosing spinal anesthesia, an interest in being alert during childbirth and fear of not waking after operation were significantly higher in those aged 25-40 and under 25 years, respectively. It seems that young women have more stress in their first experience of operation and need more support before undergoing cesarean section. The results of a study performed by Maheshwari showed that the mother's inability to choose the type of anesthesia was important (19). Fear of post-operation nausea/vomiting and pain was the main factor for rejecting general anesthesia among women aged over 40 years in the present study. That is due to the more experience of cesarean section among these women which increases their attention toward the physical complications of general anesthesia.

In the present study, the level of education had no relationship with the type of anesthesia; however, it was significantly associated with the reason for choosing the anesthetic method. The most factor influencing the rejection of spinal method by women with different education levels was the fear of needling (under diploma), fear of back pain (diploma), fear of seeing and hearing, as well as spinal injury (academic level). Regarding the

rejection of general anesthesia, the corresponding figures were the fear of non-waking up (under diploma) and fear of nausea/vomiting (academic level). It seems that the reasons are more scientific as the level of education increases. Therefore, the necessary recommendations before the operation could be more effective among women with higher education levels. In a study conducted by Naik in India, a direct association was observed between the education level and perception of patients regarding the knowledge of anesthesia. This association was stronger after the pre-operation visit by an anesthesiologist (i.e., the visit by an anesthesiologist was more effective for patients with a higher level of education (20). Further studies are recommended to investigate the effect of pre-operation visits on increasing the knowledge of patients about different methods of anesthesia and their advantages/disadvantages.

A significant relationship was also found between recommendations of non-medical persons and selection of the anesthetic method; accordingly, a great number of women receiving suggestions in favor of general or spinal anesthesia preferred undergoing that recommended method. Similar results were observed in the study carried out by Maheshwari (19). Such factors are due to no effective relationships between physicians and patients, as well as a lack of public training. It seems that the advantages of spinal anesthesia are still unknown among the general population. To increase the knowledge of the community, the patients' training should be taken into account by surgeons. In addition, public education about the advantages of regional anesthesia should be extensively performed by the media during the pre-natal educational programs and pre-operational visits. These programs can be established by the presence of other family members who have positive effects on the patients' decision-making. The patients' occupational status was also associated with the type of anesthesia; as a result, most housewives preferred spinal anesthesia, while the majority of them with government jobs selected the general method. Among housewives,



the fear of needling and back pain were the most reasons for rejecting the spinal anesthesia, whereas the most common factor among women with non-government jobs was the fear of hearing and seeing in the operation room. Women with government jobs reported the fear of spinal injury as the main factor for rejecting the spinal method. Among women who did not select the general method, fear of non-waking up was the first reason. That was not the case for women with government or private jobs. In a study performed by Maheshwari, possessing a job was a significant factor for choosing general anesthesia (19).

The effect of a job on the patients' choice requires further investigations. It is recommended to establish educational programs in administrative centers for employed women. Moreover, television programs can be effective for pregnant women who are housewives. Anesthesiologists should always consider anxiety and anesthesia for patients (21). At least, 55% of patients have anxiety for cesarean section as well as other concerns (22). Regarding the limitations of the study, one can name the descriptive nature of the research that cannot be used to correlate variables or determine cause and effect. Moreover, the patients in the private hospitals were not included in this study.

## Conclusion

The results of the present study showed that the tendency to general anesthesia among Iranian pregnant women is still slightly higher than the spinal method and needs to be more considered when compared with the developed communities. Therefore, it is recommended that women be given effective education.

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## Conflict of Interest

The authors declare no conflict of interest in this study.

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