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The Impact of Family Support on Increasing the Acceptance Rate to Spinal Anaesthesia and Reducing Preoperative Anxiety in Nullipara Pregnant Women Undergoing a Caesarean Section: A Prospective Observational Study

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ABSTRACT

Background: *Caesarean sections (CS) are common in obstetrics, with spinal anaesthesia preferred for its quick onset, reliability, and safety. Anxiety can hinder spinal anaesthesia acceptance. Involving a family member (mother, sister, husband) during administration could improve acceptance.*

Methods: *The observational study at (Beni-Suef University Hospital) received approval from the local research and ethical committee with (IRB number): FMBSUREC/04102020/ Bahr and clinical trial.gov registration number: NCT04614220. Statistical analysis performed by SPSS desktop version 24 involved Shapiro-Wilk Test to test the normality, Mann-Whitney U-test for abnormal distribution, and binominal logistic regression for decision change. The patient evaluation included medical history to ensure appropriate selection. The surgeon and anaesthetist discussed exclusion criteria, anaesthesia options, and acceptance rates with patients. Spinal anaesthesia acceptance during CS and anxiety levels (measured by VAS) were recorded.*

Results: *In this study, 110 women candidates for CS were included. The median (Inter-quartile range) age was 27 (8) years, with a median Body Mass Index (BMI) of 26 (6). Among those supported by family members, spinal anaesthesia 2nd decision was associated with lower Anxiety (5.5 ± 1.3 vs. 7.1 ± 1.4, p=0.001) and higher satisfaction (7.7 ± 1.2 vs. 6.7 ± 1.3, p=0.015) compared with those insisted on general anaesthesia. Besides, we found that with every point increase in the VAS anxiety score, there was a 64.4% (OR=0.356, 95% CI; 0.181–0.7, p=0.003) decrease in the possibility of decision change. Our study aimed to investigate the impact of involving family members during spinal anaesthesia for caesarean sections on patients' acceptance rates, anxiety levels, and satisfaction.*

Conclusion: *Our study highlights the pivotal role of family support in increasing the acceptance rate of spinal anaesthesia during caesarean sections.*

Keywords
Family, Spinal, Anxiety, Anaesthesia, Caesarean, Pregnancy.

List of Abbreviations
ASA: American Society of Anaesthesiologists, BMI: Body mass index, CI: Confidence interval, CS: Caesarean section, HR: Heart rate, IQR; Interquartile range, MAP: mean arterial blood pressure, OR: Odds ratio, SD: Standard deviation, SPO_2: Peripheral oxygen saturation, VAS: Visual analog scale.

Background
As medical technology continues to advance, more anaesthesia options are available during surgery. Two of the most common types of anaesthesia are general anaesthesia and spinal anaesthesia [1]. While both have benefits and drawbacks, recent investigations have demonstrated that preoperative Anxiety may elevate the rate of general anaesthesia instead of spinal anaesthesia, especially in young females with low educational level undergoing the caesarean section (CS) [2].

Preoperative anxiety is a prevalent condition that cases frequently encounter prior to undergoing surgery. The preoperative anxiety prevalence was 63% within obstetric patients [3]. It is a state of apprehension, fear, and worry about the upcoming surgical procedure, which can lead to physical and psychological distress [4]. Preoperative Anxiety can be caused by various factors, such as fear of pain, anaesthesia, complications, loss of control, and uncertainty about the outcome of the surgery. It can poses a significant influence on the patient's overall well-being and can affect their recovery after surgery [5]. Therefore, it is essential to identify and manage preoperative Anxiety to ensure optimal surgical outcomes and improve patient satisfaction.

There are various approaches available to mitigate preoperative anxiety, involving the utilization of relaxation approaches involving deep breathing exercises, yoga, and meditation. Additionally, seeking support from family members through open communication can also contribute to the reduction of preoperative anxiety [5,6].

Spinal anaesthesia has several advantages over general anaesthesia. It reduces the risk of complications such as lung infections or damage to teeth or vocal cords during intubation. It also allows for faster recovery [7-9]. This type of anaesthesia allows for complete muscle relaxation, making it easier for surgeons to perform complex procedures. However, general anaesthesia has some disadvantages compared to spinal anaesthesia. It requires intubation and mechanical ventilation, which can lead to several complications [10-13].

Additionally, the recovery period following general anaesthesia is prolonged, and cases may encounter negative consequences especially vomiting or nausea. This research's aim was to validate the efficacy of the presence of a close family member (mother, sister, or husband); by attending during the induction of spinal anaesthesia and keeping verbal contact with the patients. In a few cases, hand-to-hand contact is allowed. Increasing the incidence of acceptance of spinal anaesthesia during CS in nullipara.

Methods
The study was an observational study occurred in (Beni-Suef University Hospital), subject to approval from the local research and ethical committee with (IRB number): FMBSUREC/04102020/Bahr and clinical trial.gov registration number: NCT04614220. Each patient was required to provide written informed consent before their operation. The study involved a thorough examination of all patients, including medical history, to ensure proper patient selection. Prior to making a decision regarding the recommended anaesthetic, the surgeon and anaesthetist informed eligible cases about spinal and general anaesthesia alternatives and addressed exclusion criteria. Cases who initially declined spinal anaesthesia were consulted again with the option of having a close relative present for comfort during the procedure (2^{nd} decision). The rate of approval of this selection was the primary outcome, and all participants provided written consent. The number of cases who cried and anxiety levels measured with a visual analog scale (VAS) score spanning from 0 to 10 were also recorded in the study [14].

Anxiety Levels Measurement
Anxiety levels were assessed using a Visual Analog Scale (VAS) score, a widely used tool for subjective self-reporting of anxiety levels. The VAS consists of a 10-centimeter line anchored by "no anxiety" at one end and "extreme anxiety" at the other. Participants were instructed to mark the line at a point corresponding to their perceived level of anxiety at the time of assessment. The distance from the "no anxiety" end of the line to the participant's mark was measured in millimeters and recorded as the VAS score, with higher scores indicating greater anxiety.

Before the surgery, the patient's anxiety levels were measured. The anxiety levels were also recorded 10 minutes after the spinal anaesthesia procedure was completed and before they were moved from the recovery room. All cases got Ringer's solution before the surgery. Strict aseptic techniques were adhered to during the spinal anaesthesia procedure, which was conducted with the patient seated in the L3-L4 or L4-L5 space and 3 mL of heavy bupivacaine 0.5% (15 mg). Standard monitoring was established, including pulse oximetry, electrocardiography with five leads, and non-invasive arterial blood and temperature measurements.

Measurement of Patient's Satisfaction Score
Patient satisfaction was assessed using a standardized scoring system specifically designed for this study. Participants were asked to rate their overall satisfaction with the anesthesia experience immediately following the cesarean section procedure. The satisfaction score was obtained through a structured questionnaire or interview administered by trained personnel.

The questionnaire included items related to various aspects of the anesthesia experience, such as communication with healthcare providers, comfort during the procedure, and perceived

effectiveness of pain management. Each item was scored on a Likert scale, ranging from 1 (very dissatisfied) to 10 (very satisfied). The scores from individual items were then summed to calculate an overall satisfaction score for each participant.

The information to be collected includes demographic details such as age, height, weight, and BMI, as well as vital signs such as heart rate (beats per minute), peripheral oxygen saturation (Spo2), and mean arterial blood pressure (MAP) in mmHg, which was documented just before anaesthesia induction. Additionally, the rate of approval of spinal anaesthesia throughout anxiety and CS levels measured by the VAS were documented.

Inclusion and Exclusion Criteria

This study included 110 pregnant women getting elective CS at Beni-suef University Hospital.

Inclusion Criteria

Primi gravida cases between the ages of 20 and 40, the American Society of Anaesthesiologists (ASA) physical status I undergo elective CS.

Exclusion Criteria

1. Pregnancy with increased risk, such as pre-eclampsia.
2. SA is not recommended in cases of severe anaemia.
3. Urgent caesarean section.
4. Patients who have had previous spinal anaesthesia exposure.
5. Patients with education beyond the high school level.

Sample Size Calculation

The sample size calculation was based on the primary outcome of our study, which focused on the effect of involving a close relative on the rate of approval for spinal anaesthesia during caesarean sections in primigravid patients. We aimed to detect a difference in proportions using a one-sample binomial test. Using parameters recommended for sample size determination ($\alpha = 0.05$, power = 0.99), along with an estimated effect size of 0.2 derived from a previous publication [15], we computed the required sample size. The constant proportion was set at 0.5, representing the null hypothesis of no difference in approval rates between groups. The calculated sample size yielded a lower critical N of 44 and an upper critical N of 66, resulting in a total sample size of 110. This sample size provided a high level of statistical power (actual power = 0.990) while maintaining an acceptable level of significance (actual $\alpha = 0.045$).

Statistical Analysis

The researcher conducted data verification and coding before employing SPSS version 24 for analysis. The following descriptive statistics were computed: means, medians, standard deviations, interquartile range (IQR), and proportions. The Shapiro-Wilk test was employed to assess the normality of the data. The Mann-Whitney U-test was computed to examine the disparities in medians of continuous variables across non-parametric groups. To determine the decision change's significant predictors, a binominal logistic regression analysis was performed (OR, 95% confidence interval, p-value). 0.05 was regarded as a significant p-value result.

Binary logistic regression has three assumptions that should be met (Harris JK. Primer on binary logistic regression. Fam Med Community Health. 2021 Dec;9(Suppl 1):e001290. doi: 10.1136/fmch-2021-001290. PMID: 34952854; PMCID: PMC8710907). First, the observations are independent as the observations did not come from repeated measurements of the same individual. Second, there should be no perfect multi-collinearity among independent variables which will be checked by variance inflation factor (VIF). Third, there should be linear relationship between any continuous independent variables and the logit transformation of the dependent variable which will be checked using Box-Tidwell test.

Results

Briefly, 110 women candidates for CS were included. The median (Inter-quartile range) age was 27 (8) years, with a median Body Mass Index (BMI) of 26 (6), the median HR was 80 (16) beats/min, and the median oxygen saturation was 98 (2).

About 57.3% (n=63) of the included participants decided to accept spinal anaesthesia, and about 43% (n=47) rejected it and agreed to have general anaesthesia. Of those who refused spinal anaesthesia, about 62% (n=29) changed their minds and accepted it.

The mean anxiety score at baseline was 6.5 ± 1.5, and the mean patient's satisfaction score was 6.8 ± 1.3 (Table 1).

Table 1: Baseline descriptive characteristics of the studied sample

Variable	Category	Data Description
Age in years	**Median (IQR)**	27 (8)
BMI	**Median (IQR)**	26 (6)
HR (beat/min.)	**Median (IQR)**	80 (16)
SPO_2%	**Median (IQR)**	98 (2)
1st Decision	**Spinal**	63 (57.3%)
	General	47 (42.7%)
2nd Decision (N=47)	**Spinal**	29 (61.7%)
	General	18 (38.3%)
Anxiety by VAS score	**Median (IQR)**	6.5 (3)
Patient's Satisfaction Score	**Median (IQR)**	7 (2)

Data are represented as median and interquartile range (IQR). BMI; body mass index; VAS; visual analog score; SPO_2, oxygen saturation; HR; heart rate.

Results of the Included Outcomes

For the 1st decision, spinal anaesthesia 1st decision was associated with higher Anxiety (6.8 ± 1.4 vs. 6.1 ± 1.6, p=0.018) and lower satisfaction (6.5 ± 1.4 vs. 7.3 ± 1.4, p=0.005) compared with those with general anaesthesia. For the 2nd decision, among those supported by family members, spinal anaesthesia 2nd decision was associated with lower Anxiety (5.5 ± 1.3 vs. 7.1 ± 1.4, p=0.001) and higher satisfaction (7.7 ± 1.2 vs. 6.7 ± 1.3, p=0.015) compared with those insisted on general anaesthesia (Table 2).

Table 2: Determinants of the decision of the studied cohort.

1st Decision			
	Spinal (n = 63)	**General (n = 47)**	**P-value**
Age/years	26.94 ± 5.7	27.53 ± 5.3	0.494
BMI	26.79 ± 4.7	25.49 ± 3.4	0.112
Anxiety by VAS score	6.81 ± 1.4	6.11 ± 1.6	0.018*
Patient's Satisfaction Score	6.49 ± 1.4	7.30 ± 1.4	0.005*
2nd Decision (Decision change)			
	Spinal (Changed) (n = 29)	**General (unchanged) (n = 18)**	**P-value**
Age/years	27.31 ± 4.8	27.89 ± 6.1	0.939
BMI	25.48 ± 3.4	25.50 ± 3.4	0.939
Anxiety by VAS score	5.48 ± 1.3	7.11 ± 1.4	0.001*
Patient's Satisfaction Score	7.69 ± 1.2	6.67 ± 1.3	0.015*

Mann-Whitney U Test was used to compare the differences in median between groups. Data represented as mean ± SD although it was not normally distributed just to show the difference in values between groups.

Multivariable logistic regression model of the predictors of decision change for those who chose general as first decision

There were no multi-collinearity as the VIF scores were 1.086, 1.074, 1.028, and 1.03 for age, BMI, anxiety, and satisfaction respectively. Box-Tidwell test showed no specification error as the p-values of the logit of the dependent variable and the independent variables (age, BMI, anxiety, and satisfaction) are 0.537, 0.674, 0.572, and 0.342 respectively.

The binary logistic regression model was statistically significant, $\chi 2\ (4) = 20.875$, $p < .001$. The model explained 48.7% (Nagelkerke R2) of the variance in changing decision and correctly classified 78.7% of cases.

Moreover, with every point increase in the VAS anxiety score, there was a 64.4% (OR=0.356, 95% CI; 0.181–0.7, p=0.003) decrease in the possibility of decision change. On the other hand, with one–point increase in the patient's satisfaction score, there was a 100.7% (OR=2.007, 95% CI; 1.106–3.641, p=0.022) elevation in the likelihood of decision change (Table 3).

Table 3: Independent Decision Change Predictors: Multivariable Logistic Regression Model.

	OR (95% CI) *	**P-value**
• Age/years	0.947 (0.817 – 1.097)	0.466
• BMI	1.085 (0.859 – 1.371)	0.495
• Anxiety by VAS score	0.356 (0.181 – 0.7)	**0.003**
• Patient's Satisfaction Score	2.007 (1.106 – 3.641)	**0.022**

OR=Odds Ratio; CI: Confidence Interval

Discussion

In this study, we investigated the impact of involving a close relative on the approval rate for spinal anesthesia during caesarean sections among primigravid patients. Our sample size calculation, based on established parameters and an estimated effect size derived from prior research, determined a total sample size of 110, providing robust statistical power while maintaining acceptable significance levels. Through comprehensive statistical analysis, including descriptive statistics, Mann-Whitney U-tests, and binomial logistic regression, we uncovered significant insights into decision-making processes and associated factors. Our findings revealed that a substantial proportion of participants initially opted for spinal anesthesia (57.3%), while a notable portion favored general anesthesia (42.7%). Intriguingly, a majority of those initially reluctant to undergo spinal anesthesia ultimately changed their decision (62%). Furthermore, we observed associations between anesthesia choices and anxiety levels as well as patient satisfaction scores. Specifically, those opting for spinal anesthesia experienced higher anxiety and lower satisfaction initially, while those supported by family members demonstrated lower anxiety and higher satisfaction with subsequent decisions favoring spinal anesthesia. The multivariable logistic regression model further elucidated these associations, demonstrating that higher anxiety levels were significantly correlated with decreased likelihood of decision change, whereas greater patient satisfaction scores were associated with an increased probability of changing decisions towards spinal anesthesia. These findings underscore the complex interplay between psychological factors, social support, and medical decision-making in obstetric settings, highlighting the importance of holistic approaches in patient care.

From the previous evidence, Kok et al. [16] performed a meta-analysis to investigate the correlation between the patient's preoperative Anxiety and the social support received from their existing social network. Their findings suggest that there may be a slight correlation between lower preoperative Anxiety and higher social support in elective surgery cases, which differs from our results as we found a significant correlation between preoperative Anxiety and family support.

Almalki et al. [17] included 278 patients undergoing elective surgeries in a cross-sectional study to evaluate the preoperative Anxiety and its determinants' extent among adult cases. They found that patients who underwent elective surgery experienced significant preoperative Anxiety. Factors such as being younger, female, having general anaesthesia, or lacking family support were associated with higher levels of Anxiety, which is consistent with our findings.

The presence of a close family member during the administration of spinal anaesthesia has been suggested as a potential strategy to increase the acceptance of the procedure. The presence of family support can provide emotional support, reduce Anxiety and fear, and increase patient satisfaction. In the context of CS, the presence of a companion can also provide practical support, such as holding the patient's hand or helping with childcare.

Annisa et al. [18] investigated how family support impacts surgical patients' Anxiety in Indonesia. They found that the correlation between family support and Anxiety was statistically significant. Bedaso et al. [19] conducted a cross-sectional study

at an institutional level to ascertain the incidence of preoperative anxiety and identify predictors of this condition among adult patients undergoing elective surgery. A significant correlation was identified through multivariate analysis between preoperative anxiety and the potential etiological factors of anxiety, namely apprehension towards anaesthesia, apprehension regarding unanticipated outcomes of the operation, and familial concern. Depending on these results, these fears can lead to increased stress levels and negatively impact the overall birthing experience. To address these problems, the presence of a close family member, such as a mother, sister, or husband, during the procedure has been suggested as a potential solution. Furthermore, having a close family member present during childbirth can also improve communication between the patient and healthcare providers. This can result in a better knowledge of the benefits and risks associated with spinal anaesthesia and increase confidence in the procedure.

Fentie et al. [20] intended to detect the occurrence and potential causes of preoperative Anxiety in women having a planned caesarean delivery. They reported that the preoperative Anxiety's incidence in women experiencing elective caesarean delivery was found to be 67.9%. Fear of death was identified as the primary cause of preoperative Anxiety based on descriptive analysis, with a percentage of 85.2%. Other possible causes of preoperative Anxiety, such as cosmetic concerns, dependency, family concerns, and types of anaesthesia, were identified to be less than 50%.

In opposition to our findings, M. Prabhu et al. [21] examined whether the presence of a partner during neuraxial anaesthesia placement influenced the overall anxiety levels of two groups of women going through elective caesarean delivery. The researchers discovered that cases whose partners were exist in the operating room throughout neuraxial anaesthesia placement stated lower levels of anxiety throughout the study compared to cases whose partners were not exist. However, these differences were not statistically significant and do not warrant further investigation. The elevated anxiety observed in the absence of the companions during neuraxial placements demands additional research.

Conclusions

our study underscores the crucial role of family member support in influencing the acceptance rate of spinal anaesthesia among primigravid patients undergoing caesarean sections. We found that patients who had their family members present during spinal anaesthesia were more likely to accept this form of anaesthesia, highlighting the significant impact of social support on medical decision-making. While our study also observed associations between family support, anxiety levels, and patient satisfaction, our primary focus remains on the pivotal role of familial involvement in anaesthesia acceptance.

Limitations

The primary constraint of this study is its observational design, which is one-arm. Compared to experimental studies, observational studies adhere to a lower standard of evidence, are more susceptible to bias and confounding, and are incapable of establishing causality. Additionally, the subjective characteristic of the assessed results.

Declarations

Ethics approval and consent to participate

The study got approval from the local research and ethical committee (Blinded). Each patient provided the written informed consent for the participation.

Trial Registration

Ethical committee number (IRB number): FMBSUREC/04102020/Bahr. Clinical trial.gov number: NCT04614220. The trial was 1st released on 27/10/2020 and became 1st published on 03 /11 /2020. Patient enrollment on 01/03/2021.

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