Comparing the Experiences of Parturient Women With Remifentanil Analgesia and Elective Cesarean Section and Providing Improver Strategies: A Sequential Explanatory Mixed Method Study

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Study protocol

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Abstract

Background

Identifying methods that can effectively and safely improve the childbirth experience and are tailored to mothers' needs are of crucial importance. The current study aimed to compare experiences of parturient women with remifentanil analgesia and elective cesarean section and providing improver strategies for women living in the city of Tabriz, Iran.

Methods

This is a mixed-method study with an explanatory sequential approach. The first stage is quantitative and longitudinal. The study population is all parturient women who will give birth by elective C-section or vaginal painless delivery using remifentanil in private hospitals of the city of Tabriz in 2020-2021. All mothers are free to choose either method. Participants will be selected from all private hospitals using the convenience sampling technique proportioned to the number of eligible women in each hospital. Participants will be followed up to 30 days after delivery to complete the Edinburgh Postpartum Depression questionnaire.

The second stage is a qualitative study aimed at exploring the perceptions of parturient women who had either elective C-section or painless delivery (using remifentanil), including factors related to labor experiences. Data will be collected by semi structured interviews with new mothers and important others (if needed).

In the third stage, a mixed study will be performed to provide strategies for improving labor experiences. we will use an explanatory Sequential approach in order to increase the accuracy and quality of data and to use the findings to evaluate different methods of delivery.

Discussion

By comparing the experience of parturient women receiving Remifentanil analgesia and elective C-section, evidence-based improving strategies using a culturally sensitive approach can be provided. Presentation of the results obtained from this study using the mixed method may help in better understanding the issue. Also, the obtained results can be used to enhance the quality of midwifery care to be examined by health policymakers and planners.

Trial registration

This study is approved by the ethics committee of the Tabriz University of Medical Sciences (code: IR.TBZMED.REC.1399. 521). Besides, it's evaluated by relevant refers.

Background
Labor pain is one of the most severe pains a woman experiences. Experiencing labor pain is a complex subjective intertwined phenomenon with several dimensions. Contrary to acute and chronic pains, labor pain has no pathological process [1]. It is one of the most severe types of pain that, despite the development of several sedative drugs, its control is still a public health problem in most countries. Women with a history of vaginal delivery have described labor pain with terms such as severe pain, fatal pain, and unbearable pain [2]. It is so severe, in a way it's compared with finger amputation pain [1,3].

All around the world, cesarean section (C-section) rates are higher than recommended rates for 2020 goals. The World Health Organization (WHO) recommended an ideal rate of 10-15% for C-sections. According to the literature, in Iran, C-section rates are much higher than the global standards, ranging from 26 to 60%. However, in private healthcare centers, it reaches 87% [4, 5]. Fear of labor pain and recommendations of medical staff for C-section are reported as the main reasons for this high rate. Fear, concerns, and lack of awareness about labor pain may enhance couples' incline to C-section [6]. The type of delivery affects the incidence of negative and positive psychological and physical consequences of the childbirth experience. A review study reported that women who preferred C-section have a more negative view about childbirth, themselves, and their infants. They also have poor parenting behaviors and are more likely to develop postpartum mood disorders [7,8]. On the other hand, although C-section is known as a safe surgery in most countries, like any other surgery, it is associated with short-term and long-term complications such as mortality, genital tract trauma, lack of oxygenation during birth, delayed communication between mother and infant, and childhood complications. Meanwhile, the negative experience of previous childbirth is one of the most important causes of the tendency towards C-section [8].

Remifentanil is an incredibly strong pain receptor developed in the early 1990s. A study by Babenco et al. reported the successful use of remifentanil to relieve labor pain. Remifentanil has an extremely rapid clearance of approximately 3 L/min, and its half-life is about 3 minutes [9]. Remifentanil rapidly passes through the placenta; However, the placenta quickly clears it. Therefore, it's a good option, among systemic opioids, to seduce women's pain [8,9]. Women using this drug have higher birth satisfaction compared to those who received other opioids. However, they were less satisfied with epidural and spinal combined anesthesia [10]. But they are less satisfied with epidural and spinal combined anesthesia [10]. Despite the positive effects of physiologic delivery classes on reducing anxiety and improving pain control, these trainings have not always had consistent results and did not result in reduced C-section rates [11,12]. Review studies on pharmacological interventions to control labor pain have focused on the effectiveness and safety of these methods, and less attention is paid to the women's satisfaction and experience of childbirth. Several factors contribute to women's satisfaction and experience of childbirth, such as the pain control method [8].

Investigating mothers' experiences of childbirth helps caregivers to better understand their needs and expectations as well as designing effective interventions based on the identified needs to improve their satisfaction [13]. On the other hand, a negative childbirth experience can affect breastfeeding and may cause depression, post-traumatic stress disease (PTSD) [14], the decision for future pregnancy, and the
type of delivery in the next pregnancy [15]. A qualitative study has described the experience of childbirth as following "an individual life event that is a combination of physiological, mental, and psychological processes related to social, environmental, organizational, and policy-making factors" [16]. During the postpartum period, mothers are at increased risk of developing mood disorders, including sadness, depression, and psychosis. Postpartum depression is a common and treatable problem with widespread effects on mother and family, which some women experience after giving birth [17]. The type of delivery is a risk factor for developing postpartum depression [18]. Studies have reported conflicting results. Ukpong et al. reported that C-section is associated with an increased risk of developing postpartum depression [19].

Currently, one of Iran's main policies to decline the effects of the aging of the population is encouraging couples to have more children. One of the most important factors for deciding on the next pregnancy is the experience of the previous delivery. Having a negative experience and dissatisfaction with previous pregnancies decline the likelihood of future pregnancies [20]. Although painless deliveries are expanding, we could not find a study comparing the childbirth experience of women with Remifentanil Analgesia and elective C-section, either in Iran or other countries and either quantitative or qualitative. Meanwhile, analgesics with remifentanil is on the rise in Iran and different parts of the world.

Also, because of the importance of improving the quality of services provided to women in one of the critical stages of their reproductive age and not finding a mixed study on investigating the experiences of childbirth in parturient women receiving remifentanil and elective C-section and its related factors and considering the difference between environmental conditions of Iran and other countries that have studied the effects of this technique, it is necessary to investigate this issue by a combined approach. Mixed studies combine quantitative and qualitative approaches to have a better understanding of the research subject, compared to when each of these approaches is used separately [21]. The current study aims to determine the mean score of labor experience, postpartum depression score, and maternal and neonatal outcomes in parturient women with Remifentanil Analgesia and elective C-section in the quantitative stage. Then, we will investigate the childbirth experience of participants by interviewing them one month after delivery in order to provide improving strategies. In this study, we will use an explanatory Sequential approach in order to increase the accuracy and quality of data and to use the findings to evaluate different methods of delivery.

**Study Aims**

The main goal: Comparing the experiences of parturient women with remifentanil analgesia and elective Cesarean Section and providing improving strategies.

Goals of the quantitative stage

1- Comparing the mean score of labor experience in the study groups 24 hours after delivery (parturient women with remifentanil analgesia and elective Cesarean Section)
2- Comparing the mean score of postpartum depression one month after delivery in the study groups (parturient women with remifentanil analgesia and elective Cesarean Section)

Objectives of the quantitative section

1- Comparing Apgar score on first and fifth minute in two groups. (Infants give birth with remifentanil analgesia and elective Cesarean Section);

2- Comparing neonatal need for cardiopulmonary resuscitation among study groups. (Infants give birth with remifentanil analgesia and elective Cesarean Section);

3- The association between sociodemographic and midwifery characteristics with childbirth experience among the study groups (parturient women with remifentanil analgesia and elective Cesarean Section).

The goal of the quantitative stage

Exploring the experience of parturient women with remifentanil analgesia and elective Cesarean Section

The goal of the third stage

Providing strategies for improving labor experiences

Methods

Study design

This is a mixed-method study with an explanatory sequential approach. The first stage will be quantitative and longitudinal and intended to estimate the mean score of labor experience and postpartum depression score, neonatal outcomes, and factors that influence these scores in parturient women with Remifentanil analgesia and elective C-section in private hospitals of the city of Tabriz.

The second stage, which is qualitative, intends to explore the perception of parturient women with Remifentanil analgesia and elective C-section and factors related to labor experience. In the third stage, in order to provide strategies for improving labor experience, a mixed study will be performed by reviewing the literature and nominal group method.

Quantitative stage

Study design and participants

This is a quantitative and longitudinal study. The study population is all parturient women who will give birth by elective C-section or vaginal painless delivery using remifentanil in private hospitals of the city of Tabriz (Fig 1).

Inclusion criteria
Living in the city of Tabriz, the first or second delivery, uncomplicated singleton pregnancy, women with Remifentanil Analgesia and elective C-section, and gestational age of 37-42 weeks.

**Exclusion criteria**

Previous cesarian section, major diseases such as cardiovascular disease, diabetes, chronic hypertension, preeclampsia, etc., and obstetric problems such as placenta Previa, fetal distress, placental abruption, having a history of depression and receiving medication (according to the person's statement), the occurrence of important stressful events during the past six months in the family such as the death of a relative, divorce, etc., and obtaining a score higher than 12 in EPDS questionnaire at 35-37 weeks of gestation.

**Sample size**

The sample size was determined using the study by Barber et al., and based on the childbirth experience the following variables were considered: $m_1$ (SD1) = 49.1(10.1), $m_2$ (SD2) = 50 (8.7), $\alpha$=0.05, and power=%95. The sample size was calculated as 63 subjects in each group. However, by considering an attrition rate of 10%, the sample size was increased to 140 (70 in each group) [22].

**Sampling**

In order to collect quantitative data, first the researcher will obtained the rate of vaginal delivery in private hospitals. Then the researcher will visit midwifery clinics of private hospitals to identify pregnant women with a gestational age of 35-37. Participants will be selected using the convenience sampling method. After providing necessary explanations, potential subjects will be invited to participate in the study, after evaluating against inclusion and exclusion criteria. The sampling will continue until selecting the required participants.

The objectives and method of the study will be fully explained to eligible participants, and, if agreeing, informed written consent will be obtained. Individual unable to fill the questionnaire will be interviewed verbally. Participants will be ensured about the confidentiality of the information. Besides, they will be ensured that the research team won't mention their names. The sociodemographic and EPDS questionnaires will be filled using an in-person meeting. The participants will be followed up to delivery. They will fill the labor experience questionnaire and midwifery-neonatal outcomes checklist 24 hours after delivery. In the second stage of follow-up (one month after delivery the researcher will complete the postpartum).

**Tools and data collection**

Quantitative data collection method and tools

Quantitative data will be collected using the inclusion and exclusion criteria checklist, socio-demographic and obstetrics record questionnaire
Edinburgh Postpartum Depression questionnaire, childbirth experience questionnaire, and obstetrics neonatal outcomes checklist.

Socio-demographic questionnaire: It contains items such as age, age of spouse, education level, socioeconomic status, etc. This questionnaire should be completed on the admission day.

Obstetrics Questionnaire: It contains items such as the number of pregnancies, pregnancy history, place of the previous delivery, etc. It will be completed immediately after entering the study.

Edinburgh's Depression during Pregnancy Questionnaire (Cox et al., 1987)

This 10 item questionnaire is used to detect depression during pregnancy. The items are scored on a four-point-Likert scale, ranging from low to high intensity (1, 2, and 4). Also, there is a seven-point-Likert scale, ranging from high to low intensity (3, 5, 6, 7, 8, 9, 10). The total score is the sum of each item, ranging from zero to 30. Those with a score higher than the cut-off threshold of 12, suffer from different severity depression [23]. This questionnaire is psychometrically evaluated in Iran by Montazeri et al. [24,25].

Labor Agentry Scale (Simmons & Hodnett, 1987)

This 10 item questionnaire is developed to measure the mother's feelings during childbirth. The items are scored on a seven-point-Likert Scale, ranging most often [7] to never or never in most cases [1]. It has six positive and four negative items. The total score ranges from 10 to 70, and the higher the score, the higher is the likelihood of having a positive experience. Madadi et al. have confirmed its validity and reliability. They reported a content validity index (CVI) of 0.91 and a content validity ratio (CVR) of 0.98.

Data Analysis

Data will be analyzed using SPSS version 21 For data with a normal distribution, descriptive statistics including frequency (percentage) and mean (standard deviation) will be used. For data that are not distributed normally, median (25 to 75 quartile) will be used to describe demographic characteristics. To compare the depression and childbirth experience of the two groups, one-way ANOVA will be used for one side analyses. Concerning multivariate analyses, multivariate linear regression, with controlling sociodemographic and obstetrics characteristics and basic depression score, will be used to compare depression and childbirth experience among the study groups.

Qualitative Stage

Study Design

In this stage, conventional Content Analysis will be used to analyze qualitative content. The main advantage of this approach is obtaining direct information without imposing predetermined categories or theories [95].

Sampling and data collection
Based on the mean scores of the childbirth experience (obtained at the quantitative stage), extreme cases (upper and lower 10%) will be selected. Participants will be selected using the purposive sampling technique (i.e. women with extreme scores who are willing to express their experiences about labor will be selected). Interviews will be performed one month after delivery.

Data Analysis

Qualitative content analysis will be used to analyze the data. It is a research method for interpreting textual data by a systematic classification process, coding, and identifying themes and patterns [26]. Content analysis is more than just extracting objective contents from textual data. In this way, themes (hidden patterns) can be extracted from collected data [27]. The core of the qualitative content analysis is the creation of classes, a group of contents that have commonalities. According to Granheim and Landman (2004), the difference between class and theme is that the "class" answers the question of "what" and can be defined and identified as a string in all codes. Classes may include a series of sub-classes with different levels of abstraction. Themes intend to answer the question of "how". The theme is a semantic strand extracted from semantic units, codes or classes at different levels of interpretation. In this research, the notes obtained from interviews are classified into classes and themes [28].

The qualitative content analysis method contains three approaches of conventional, directed, or summative. In this study, the conventional approach will be used. In this method, data analysis starts by reviewing all transcripts carefully to achieve immersion and obtain an overall understanding.

Then, transcripts should be reviewed carefully to extract codes that seem to carry the main thoughts or concepts. The analysis continues by analyzing the primary thoughts of the researcher. As this process continues, themes that reflect more than one main thought appear. These themes often are directly extracted from the transcript. The codes are then categorized based on their differences and relationships with each other. The created classes are used to organize and categorize codes into meaningful categories. Ideally, the number of codes ranges from 10 to 15 [26].

Third Stage

Methodology

According to the main goal of this study (i.e. developing strategies to improving labor experiences concerning the most common cause of negative labor experiences (pain)), the nominal group method will be used. In most cases, obtaining the views and opinions of health professionals using a systematic and scientific process is of crucial importance for health policymakers.

In total, eight multidisciplinary experts in the field of health will participate in the present study, including University professors (from Midwifery & Reproductive health, Obstetrics & Gynecology and Health departments), researchers, and policymakers and psychiatry, anesthesiology, sociology, and anthropology experts in health and medicine. All members of the research team will present at meetings. The researcher will run the meeting as the facilitator.
A week before the nominal group meeting, preparations will be made. In order to maximize the spectrum of investigated views and opinions, members of the meeting will have various skills, but they should be related to reproductive health.

Session materials will include a pen and paper for all members, a Flip chart, markers, a voice recorder, and U-shaped tables.

In the present study, phases of the nominal group method will be as follows:

Step 1: Opening the session

In this step, after acknowledging all participants for their presence, the steps of the meeting will be explained to them. Then, the objective of the meeting (“the most appropriate strategies for improving labor experience?”) will be discussed.

Step 2: Silent generation of ideas in writing

All participants will have 10 minutes to write their ideas. This step will take place in silence, and there will be no discussion among the members of the group.

Step 3: Round-robin recording of ideas

At this step, the ideas of the members will be written on the Flip chart by the secretary of the meeting one-by-one. All participants will have an equal opportunity to present their ideas. All ideas will be coded sequentially.

Step 4: Serial discussion on the ideas

At this stage, all ideas will be discussed and clarified, based on the order written on the chart. Repetitive ideas will be removed. Also, ideas with a similar concept will be merged or, if not clear, the person should explain more. The process continues until discussing all ideas.

Step 5: Voting to select the most important ideas

At this stage, participants are requested to select the five most important ideas of the list and write each one on an index card. In this way, the most important idea, ranked as the first, will have a score of five, then the second important idea will score four, and so on. Then all cards will be collected, and the scores will sum up on the flip chart.

Step 6: Discussion on the selected ideas

It worth noting that combining findings of quantitative and qualitative sections is useful for providing the final strategy. To ensure validity, robustness, and accuracy of the findings, heterogeneity of participants of the nominal group was observed. This issue also helps in obtaining a wide spectrum of opinions. Also, the principles of holding and managing nominal group meetings were observed. It was tried to prevent
the dominance of some particular participants because of their number or strength. For this purpose, all members of the meeting were given equal time to express their opinions. In addition, the validity and reliability of the results were improved by using predetermined criteria for selecting participants and employing a detailed predetermined question [33,34].

**Ethical considerations**

The current study is approved by the Ethics Committee of the Tabriz University of Medical Sciences (Code: IR.TBZMED.REC.1399. 521). Participants will be ensured about the confidentiality of their information. They will be informed that they can withdraw from the study at any time, without influencing the quality of services that they receive. At both quantitative and qualitative stages, informed written consent will be obtained from participants.

**Discussion**

Women's childbirth experience depends on various social, environmental, and organizational factors as well as policies. The experiences that women gain during the delivery process are considered as one of the important outcomes of childbirth, and these experiences remain with them throughout their lives [35]. The WHO stated that receiving support from loved ones during labor and delivery can positively influence the childbirth experience [36]. According to a systematic review, continuous support during labor is the most important factor affecting the experience of childbirth and is important for paying attention to the needs of the mother during the labor and delivery phase. There is a strong association between the negative experience of childbirth and postpartum depression. Besides, the negative experience of childbirth affects maternal behaviors and maternal anxiety [37].

Childbirth is one of the most challenging psychological events in a women's life, 10-34% of mothers have faced negative birth experiences [38]. Negative childbirth experience is associated with PTSD, disruption of interpersonal relations, inefficiency in maternal-neonatal relations [39], reduction in exclusive breastfeeding [40], improper use of maternity and neonatal care services [41], and fear of childbirth and increased tendency to elective C-section in future pregnancies[8]. Labor pain is one of the most severe pains a woman experiences. Receiving appropriate support and care during labor and delivery is associated with a positive childbirth experience, even in the presence of serious complications.

Memories related to childbirth last for several years in the mind of the mother [16]. A negative experience of childbirth is associated with low quality of life, the persistence of pain in mind, and PTSD. Besides, it may lead to a decreased tendency to pregnancy in the future and postpartum depression. [42].

Most women with a history of remifentanil during labor have satisfactory childbirth compared to other opioids. However, compared to those who received combined anesthesia of spinal and epidural, the remifentanil group was less satisfied [10].
Despite the positive effects of physiologic delivery training intended to reduce anxiety and increasing the sense of pain control, conducted studies have reported conflicting results, and these trainings were not successful in reducing C-section rates [11,12]. Review studies on pharmacological interventions for labor pain relief have focused on the effectiveness and safety of these methods, and less attention has been paid to women's satisfaction and experience of childbirth. Meanwhile, several factors can influence women's satisfaction and experience, including the applied painless method for labor [8].

This proposal, which has three stages, has several strengths. We hope this study will fill important knowledge gaps in reducing fear of childbirth and having painless childbirth. We will develop strategies for improving the childbirth experience by comprehensively reviewing the literature as well as based on the findings of quantitative and qualitative stages. These strategies can be used by experts and pundits. Therefore, it is expected to have important clinical consequences. Analgesia with remifentanil is increasing in Iran and different parts of the world. Besides, in Iran, high rates of C-section have no scientific reason except the fear of labor pain. It worth noting that Iran has the highest rate of C-section in the East Mediterranean region of the WHO. However, no quantitative or qualitative study has investigated the experiences of parturient women with remifentanil analgesia and elective C-section. Therefore, the current, with a mixed approach, is designed to achieve a deeper understanding by combining various approaches and methods.

Evaluating women's experiences and comparing maternal and neonatal outcomes of the aforementioned techniques would be useful for having a better understanding of this issue. Besides, the results can be used for promoting the quality of midwifery care by health policymakers and planners.

**Abbreviations**

LAS: labor agency scale; C-section: caesarean section; CVI: content validity index ; CVR: content validity ratio; SD: standard deviation.

**Declarations**

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**Authors' contributions**

RD, SH, HP, RN, and NS contributed to the design of the protocol. NS, SH, and RD contributed to the implementation and analysis plan. NS, SH, RN and RD have written the first draft of this protocol article, and all authors have critically read the text and contributed with inputs and revisions, and all authors read and approved the final manuscript.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Written informed consent will be obtained from each participant. This protocol has been approved by the Ethics Committee of the Tabriz University of Medical Sciences, Tabriz, Iran (code number: IR.TBZMED.REC.1399.521)

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests

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References


Figures
Figure 1

Study visual diagram