Comparing the Experiences of Birth Experiences Women With Remifentanyl 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 are effective and safe while also compatible with maternal needs and improving the delivery experience is important. Since pharmacological interventions provide better pain alleviation for women during labor when compared to nonpharmacological interventions, in case the former also improves women satisfaction with the labor experience, care providers can propose this method for mitigating the women's pain during labor. The aim of this study is to compare the experience of parturient women between remifentanil analgesia and elective C-section, as well as proposing ameliorating strategies in Tabriz city, Iran.

Method

The present research is of mixed methods research type with a sequential explanatory approach. The first stage is quantitative and longitudinal. The target population consists of parturient women receiving elective C-section and vaginal labor through remifentanil analgesia in the private hospitals of Tabriz city. The sampling will be performed from all private hospitals of Tabriz city as available sampling. They will be chosen from each hospital based on specific ratios in relation to the eligible women according to the inclusion criteria, and then assigned into two groups (elective C-section and parturient women receiving remifentanil). Demographic characteristics as well as Edinburgh's depression test during pregnancy questionnaires plus labor agency scale (LAS) as well as the checklist of maternal and neonatal outcomes within 24 hours postdelivery will be completed by the researcher. The subjects will be followed up for up to 30 days postdelivery in order to complete the Edinburgh depression questionnaire. The second stage of study is qualitative performed to interpret parturient women's perception about elective C-section and Remifentanil anesthesia regarding different aspects and the factors associated with delivery experience. The sampling will continue until data saturation, i.e. no new information or code is received. Based on the results of the total mean score of delivery experience, which will be obtained in the quantitative section, the extreme cases will be chosen. For this purpose, at both ends of the total score spectrum of the delivery experience, the women acquiring the 10% upper and lower extreme total score of delivery experience will be chosen as the extreme cases. Purposeful sampling will be done on mothers belonging to extreme cases and who are willing as well as able to express their experiences. In the third stage, in order to provide ameliorating strategies for delivery experience, after combining the quantitative and qualitative studies, a review of the literature and then nominal group technique will be used.

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.

Plain English Summary

Labor pain is regarded as one of the most severe types of pain, which in spite of applying various pain reliever drugs, its control is still one of the major health problems in most countries.

Based on the review performed on labor analgesia, no research was found focusing on labor experience with Remifentanyl and comparing it with elective C-section across Iran or worldwide. Meanwhile, analgesia with Remifentanyl is progressively growing in both Iran and worldwide. Promoting the quality of services provided to women in one of their most critical times of their life [labor] and absence of a mixed study on interpreting the labor experience with Remifentanyl analgesia and elective C-section as well as the associated factors concerning the special conditions of Iran regarding high C-section, have all prompted us to conduct a research on this issue using a mixed approach.

The present research is of mixed methods research type with a sequential explanatory approach. The first stage is quantitative and longitudinal. The target population consists of parturient women receiving elective C-section and vaginal labor through Remifentanyl analgesia in the private hospitals of Tabriz city. The method of the qualitative phase of the study is a qualitative content analysis with a conventional approach. Concerning the ultimate goal of this study, i.e. developing strategies for improving the delivery experience regarding the most common causes of adverse labor experience [i.e. Pain], for determining suitable strategies, the nominal group technique will be used.

Background

The rate of labor through C-section is higher than the rate recommended for 2020 goals worldwide. According to World health organization recommendation, the prevalence of C-section should not be more than 10-15% of all labors. On the other hand, based on different studies, the rate of C-section in Iran is very high, and averages between 26 and 60%. These figures have been reported to be up to 87% and even more in private centers [3, 4]. The fear of pain through natural labor and the recommendations made by the healthcare team for undergoing C-section are the main reasons for cesarean with no medical necessity in Iran. Fear, worry, and deficient awareness about labor pain may predispose the couple to choose C-section over natural delivery [5].

The type of labor chosen also affects the rate of incidence of these psychological and physiological effects. A review study reported that the women who gave birth through C-section have a more negative view to their delivery, themselves, and their infant. Further, they have weaker parental behaviors, and are more likely to experience postpartum mood disorders [6, 7]. Meanwhile, although in most countries, C-section has been known as a risk-free surgery, as with other types of surgery, cesarean is also associated with both short-term and long-term complications such as mortality, obstetric fistula, birth asphyxia, delay

in the relationship between the mother and infant, as well as childhood complications. Meanwhile, the unfavorable/negative experience of previous labor in women has been reported as one of the most important reasons for women preferring to undergo caesarean-section [7].

Remifentanyl is a very potent pain receptor, synthesized in the early 1990s. In the study by Babenco et al., remifentanyl was used successfully for alleviating labor pain. The onset of action of Remifentanyl is within one minute with a short half-life of around 3 min [8]. It rapidly crosses the placenta, yet it is quickly metabolized and does not reach the fetus. Therefore, it is a suitable choice of systemic opioids in order to alleviate the labor pain [7,8]. Most women who are administered Remifentanyl during labor have expressed greater satisfaction with delivery compared to other opioids. However, regarding the comparison of mixed Remifentanyl and epidural and spinal anesthesia, the pure Remifentanyl group had less satisfaction [9]. Review studies performed on pharmacological interventions for mitigating the labor pain have focused on the effectiveness and safety of these methods, but they have paid less attention to the women's experience and satisfaction with delivery. On the other hand, this experience and satisfaction can be affected by various factors including the method of analgesia during labor [7].

The postdelivery period is when there is the maximum risk for incidence of mood disorders including sorrow, depression, and psychosis. Postpartum depression is a common and treatable problem with massive effects on both the mother and family. It is experienced by some women after giving birth to their child [10]. The type of delivery has been known as one of the risk factors for postpartum depression [11]. The research conducted in this regard has shown different and sometimes contradictory results. The results of a study by Apong et al. indicated that the women who give birth to their child through C-section have greater chance to develop postpartum depression [12].

Currently, one of the policies of Iran to tackle the population aging and reduction is encouraging couples to increase delivery. One of the important factors for decision-making in the next pregnancy is the type of experience acquired from the current delivery. When a woman has a negative experience and dissatisfaction with the previous delivery, this reduces the probability of decision-making for another pregnancy [13].

Based on the review performed on labor analgesia, no research was found focusing on labor experience with Remifentanyl and comparing it with elective C-section across Iran or worldwide. Meanwhile, analgesia with Remifentanyl is progressively growing in both Iran and worldwide. Promoting the quality of services provided to women in one of their most critical times of their life [labor] and absence of a mixed study on interpreting the labor experience with Remifentanyl analgesia and elective C-section as well as the associated factors concerning the special conditions of Iran regarding high C-section, have all prompted us to conduct a research on this issue using a mixed approach.

In mixed studies, quantitative and qualitative approaches are usefully combined with each other. This combination provides a better understanding about the issue when compared to each approach is used individually [14]. The present study will be performed to determine the mean score of labor experience and postpartum depression score as well as maternal and neonatal outcomes in parturient women giving

birth through Remifentanil analgesia and elective C-section in the quantitative part, and interpreting the experience of women regarding their delivery experience in the qualitative part through interview with women one month postdelivery. In the mixed part, ameliorating strategies for delivery experience will be provided. In this study, sequential explanatory mixed approach will be used, so that using various approaches, the accuracy and quality of data would increase, and the research findings would be used for assessing various delivery methods

STUDY AIMS

Comparing the experience of parturient women administered Remifentanil analgesia and undergoing elective C-section as well as providing ameliorating strategies for the delivery method

The specific objectives of the quantitative phase are:

1. Comparing the mean score of the delivery experience across the studied groups 24-hour postdelivery (delivery with Remifentanil analgesia, elective C-section)
2. Comparing the mean postpartum depression score one month after the delivery across the studied groups (delivery with Remifentanil, elective C-section)

The secondary objectives of the quantitative phase are

1. Comparing the first minute and fifth minute neonatal Apgar score across the studied groups (delivery with Remifentanil, elective C-section)
2. Comparing the need to neonatal resuscitation across the studied groups (delivery with Remifentanil, elective C-section)
3. Determining the relationship between demographic plus midwifery characteristics and women's labor experience across the studied groups (delivery with Remifentanil, elective C-section)

The specific objective of the qualitative phase is

1. Interpreting the parturient women's experience receiving Remifentanil analgesia and undergoing elective C-section

The specific objective of the third phase

Presenting strategies to improve delivery experience

Method/design

Study design

The present research is a mixed methods research performed through sequential explanatory approach. The first stage is quantitative and longitudinal to determine the mean score of delivery experience and

postpartum depression, as well as some associated factors in parturient women undergoing elective C-section and receiving Remifentanyl anesthesia in the private hospitals of Tabriz city. The second stage of study is qualitative performed to interpret the parturient women's perception receiving elective C-section and Remifentanyl anesthesia from different aspects and the associated factors with delivery experience. In the third stage, in order to present strategies to improve the delivery experience, the quantitative and qualitative studies will be mixed, literature will be reviewed, and the nominal group technique will be used (Figure 1).

Quantitative study

Study design

The quantitative stage of study is longitudinal. The target population is parturient women chosen for elective C-section and vaginal delivery through Remifentanyl analgesia in private hospitals of Tabriz city.

Inclusion criteria

Residence in Tabriz, women with first and second deliveries, women giving birth with Remifentanyl analgesia and elective C-section, pregnancy age 37-42 weeks.

Exclusion criteria

Multiple pregnancies, suffering from important diseases such as cardiovascular disease, diabetes, chronic hypertension, preeclampsia, etc., midwifery problems including placenta previa, fetal distress, decollement, history of depression with drug therapy [according to person's self-expression], incidence of an important stressful accident over the past six months in the family such as the death of one of the relatives, divorce from the partner, etc. acquiring a score higher than 12 in EPDS questionnaire at 35-37 weeks of pregnancy.

Sample size

The sample size was calculated as 63 for each group based on this study by Barber et al., and according to the labor experience variable considering m_1 (SD1) = 49.1 (10.1), m_2 (SD2) = 50 (8.7), $\alpha=0.05$, and power=95%. Considering 10% attrition, the final sample size was determined as 70 in each group and 140 in total [15].

Sampling

In order to collect quantitative data, after acquiring the ethics code, first the researcher will obtain the rate of natural delivery in the private hospitals individually. Next, the researcher will show up in the midwifery clinic of the relevant hospital and choose the eligible women who are in their 35-37 weeks of pregnancy through convenient or available sampling. After giving the necessary explanations about the research, the eligible individuals (according to the checklist of inclusion criteria) will be invited to participate in the research. Note that the sampling will continue until data saturation [in terms of the quota determined at

the beginning of the research). In case the women are confirmed to meet the criteria, the study goals and methods will be explained completely. Then, if they wished to participate, written informed consent form will be obtained from them. Regarding illiterate subjects, the researcher will explain the consent form in a very simple and understandable way to them. Then, if they consented to participate in the study, fingerprint will be obtained. The participants will be assured that their names and information would be kept confidential, and reporting of the results will be done anonymously. During the in-person meeting, demographic characteristics questionnaires along with the EPDS questionnaire will be completed in a relatively quiet environment. The researcher will follow up the participants and 24 hours postdelivery, they will complete delivery experience questionnaire as well as the maternal and neonatal outcomes checklist. In the second stage of follow-up (one month postdelivery during the third visit in healthcare centers), the researcher will complete Edinburgh's postdelivery depression for a second time.

Scales and data collection

In order to collect the quantitative data, inclusion and exclusion criteria checklist, demographic and midwifery characteristics questionnaire, Edinburgh's postdelivery depression questionnaire, delivery experience questionnaire, and maternal plus neonatal outcomes checklist will be used.

The demographic characteristics questionnaire:

Socio-demographic and obstetric characteristics questionnaires

This questionnaire includes questions such as age, spouse age, level of education, socioeconomic status, etc., and will be completed at the baseline of study. Also items about the number of pregnancies, history of pregnancies, place of delivery, etc., which will be completed immediately after enrollment in the study.

Edinburghs Depression during Pregnancy

This questionnaire is used for measuring depression during pregnancy and postdelivery, developed by Cox et al. (1987). This instrument consists of 10 four-option items, in some of which the options are ordered from low to high (items 1, 2, and 4), while in some others from high to low (items 3, 5, 6, 7, 8, 9, 10). The options of each item will claim a score from 0 to 3 based on the severity of symptoms. The score acquired by the person is obtained through summing up the scores of the 10 items, which can vary between zero and 30. Mothers acquiring scores higher than the threshold value of 12 have depression with different severities [16]. The psychometric measurements of this questionnaire have been done by Montazeri et al. in Iran [17, 18].

Labar Agentry Scale

It will be used for measuring the delivery experience. This questionnaire was developed by Simmons and Hodnett in 1987. It captures the mother's feelings during the labor. It includes 10 items, containing six positive and four negative items. It is based on a 7-option Likert scale, with 7 representing almost most of

the time and 1 indicating never or almost never. The total score ranges from 10 to 70, with higher scores indicating greater probability of positive experience. The reliability and validity of this instrument have been confirmed in the study by Madadi et al. According to them, the content validity index (CVI) was 0.91, and the content validity ratio (CVR) was 0.98.

Data analysis

In order to analyze the quantitative data, SPSS 24 will be used. For describing the demographic and midwifery characteristics, descriptive statistics including frequency (%), mean (SD) in case of data normality and median [quartile 25-75] in case of data abnormality would be used. In order to compare the depression and experience of delivery across the studied groups, in bivariate analysis one-way analysis of variance, and in multivariate analysis, multivariate linear regression will be used while controlling the demographic and midwifery characteristics as well as the basic depression score.

Qualitative study

Study design

The method of the qualitative phase of study is a qualitative content analysis with a conventional approach. The main advantage of qualitative content analysis based on a conventional approach is obtaining direct information from study without imposing any predetermined issues or theories [95].

Sampling and data collection

Based on the results of the total mean score of the delivery experience obtained in the quantitative section, the extreme cases will be chosen. For this purpose, on both sides of the spectrum for the total score of delivery experience, the women acquiring the top or bottom 10% extreme scores for the total delivery experience score will be selected as the extreme cases. The sampling will be purposeful, which means that the women belonging to the extreme cases, who are also willing and able to express their experience about the delivery will be chosen. One month after the delivery, the women will be interviewed.

Data analysis

In order to analyze the data, qualitative content analysis method would be used. Content analysis is a research method for interpreting textual data through systematic classification, coding, and identification of the themes and patterns [19]. Content analysis is something beyond extracting objective content adapted from textual data. In this way, the themes and hidden patterns can be unveiled from inside the content of the participants data in the study [20]. The main core of the qualitative content analysis is creating classes. Class is a group of contents with some commonalities. The difference between class and theme according to Granheim and Landman [2004] is that class answers to the question "what" and can be defined and identified as a thread in all codes. Classes can include a series of subclasses with different abstract levels. On the other hand, the theme answers the question "how". In this research, the notes obtained from interviews will be converted to classes and themes [21].

In the qualitative content analysis method, three approaches including conventional, directional, and cumulative are considered. In this study, the conventional approach will be used. In this method, data analysis begins by reading the entire text repeatedly, such that the researcher is immersed in the data and obtains a general sense of the text. Next, the texts will be read word by word for code extraction. First, the objective words which seem to cover the main thoughts or concepts are identified. Thereafter, the researcher proceeds the text through taking notes from the initial analysis as well as her primary beliefs and thoughts. As the process goes on, the labels of codes, which reflect more than one main thought, emerge. They are often extracted directly from the text. Next, the codes are classified based on the differences and their association with which other. The created classes are used to organize and group the codes into meaningful groups. Ideally, the number of classes is 10-15, in order to be adequate for classifying a large number of codes [19].

Third stage

Method of implementation

Concerning the ultimate goal of this study, i.e. developing strategies for improving the delivery experience regarding the most common causes of adverse labor experience [i.e. Pain], for determining the suitable strategies, the nominal group technique will be used. In many cases, acquiring the views and ideas of healthcare experts and scholars in a systematic and scientific way are very important for the health policymakers.

The participants of the present meeting will be 8 to 10 healthcare multidisciplinary experts and scholars. These people include University professors, researchers, and policymakers with specialized majors of obstetrics and gynecology, health promotion, reproductive health, psychiatric, anesthesia, and sociology. The participants of this meeting will be chosen and invited based on their rich formation and having experience regarding reproductive health. In addition, all of the members of the research team will take part in the meeting. Finally, the researcher will round the meeting as a facilitator.

The preparation for implementing the nominal group meeting will be done in one week before the meeting. The invited meeting members have various specialized areas associated with reproductive health, so that it would be possible to expand the spectrum of various views regarding the investigated issues and capture as many divergent ideas as possible. The required materials include pen and paper for each member, a flipchart, marker, recorder, and a U-shaped table. In the present study, the phases of the nominal group technique will be implemented as follows:

1. Opening the session and introduction: in this phase, the facilitator while welcoming the participants will describe the role of each person, goals of the meeting, importance of tasks, and the significance of participation of all in the activities as well as the nominal group technique process for all of the meeting members. The researcher will provide the experts with the results of the quantitative and qualitative phases of this study in order to develop proper strategies alongside the rich experiences of the experts themselves. In addition, while presenting the results of study, the researcher also

reviews the literature related to the strategies for improving the delivery experience worldwide for providing more knowledge to the experts. Note that at this stage, the facilitator will express the regulations of the nominal group meeting for the members.

The regulations include:

1. Any expression of idea by the group members is approved. The views of each person are written with the words expressed by them. When one of the members of the group expresses an idea, no one would interrupt them. The views of anyone will not be criticized either. No question would be posed about the viewpoints, unless for more clarification.
2. Silent generation of ideas in writing: the meeting members will respond to the main research question for 5 to 10 minutes: "based on the results and findings presented and your own rich experiences, what are the strategies that you suggest for improving the women's experience?" In this phase, the meeting members are asked to express and write their ideas silently based on the information and results of studies performed and their own personal experience. They would have no interaction with other members with regards to the answer to the question.
3. Round Robin recording of ideas: in this phase, each of the members of the meeting will read their ideas. Without any discussion, the facilitator will write the opinions of members on the flipchart. In this phase, all of the meeting members will have equal opportunity to express their ideas. This stage will last 20 minutes. Then, the participants are asked whether all of their ideas have been expressed or not.
4. Serial discussion on the ideas: in this stage, each of the ideas will be discussed and clarified. In case an idea was duplicate, it would be removed. Also, the ideas with the same concept will be merged together. Finally, in case an idea was not clear, it would be clarified by the person presenting that idea or other experts participating in the meeting. This will continue until there would be no ambiguity about the presented ideas.
5. Voting to select the most important ideas: in this phase, the members are asked to list five important ideas from their views from among the items remaining from the previous phase, whereby they would allocate score 5 to 1 regarding the importance. After the final voting, the facilitator will sum up the scores. The items acquiring a score below two will be removed from the final list.
6. Discussion on the selected ideas: this stage is not an essential step for the nominal group technique, though it is recommendable. This stage helps the group consolidate the findings further. In this stage, the available strategies will be classified according to the ideas of experts.

In the nominal group meeting, in order to ensure the reliability, consistency, and accuracy of findings (reliability and validity), the heterogeneity of the participants (various specialized areas) in the meeting will be carefully observed. The goal is to increase the range of responses and spectrum of the views propounded on the discussed issues as much as possible. Furthermore, the principles of organizing and managing the nominal group meetings will also be carefully observed. Attempts will be made to prevent dominance of some members in the meeting because of their number or authority. For this purpose, equal

time will be given to all members of the meeting to express their ideas. In addition, the reliability and validity of the results will improve using predetermined criteria for selection of the participants and usage of one precise predetermined question [22, 23].

Ethics approval and consent to participate

This study has been approved by the ethics committee of Tabriz University of medical sciences. The participants will be assured about the confidentiality of the information and names when reporting the results. It will also be explained that they are allowed to quit this study at any stage they wish, and their withdrawal is free, whereby no change will occur in provision or quality of routine services provided to them. Written informed consent form will be obtained from all participants in both quantitative and qualitative status.

Discussion

Delivery experiences are affected by various social, environmental, and organizational issues as well as policies. The experiences women acquire during the delivery process are considered as one of the important delivery outcomes, which will sustain over the life of these women [24]. World Health Organization states that if mothers are supported by those with whom they feel comfortable during labor and delivery, they will have satisfaction with their labor [25]. Based on a systematic review study, constant support during labor is the most important factor affecting the delivery experience as well as the attention to the mother's needs during the labor and delivery stage. There is a strong relationship between negative experience of delivery and postpartum depression, where the negative experience of labor also affects maternal behaviors and maternal anxiety [26].

Delivery is one of the most challenging psychological events in the mother's life. A total of 10-34% of all childbearing for women are associated with negative childbearing experience [27]. Negative delivery experience is also associated with posttraumatic stress disorder (PTSD), impairment in establishing interpersonal relationships, inefficacy in the maternal and neonatal relationship [28], reduced exclusive breast-feeding [29], improper use of maternal and neonatal care services [30], fear of delivery, and increasing tendency to elective C-section in subsequent pregnancies [7]. If mother during the labor receives suitable care and support, even in spite of the serious complications of delivery, she would have positive experience of it, where the labor experiences sustain clearly in the mind of mothers even after many years [16]. On the other hand, negative experience of delivery is associated with low quality of life, sustenance of pain in the mind, and PTSD, and may lead to reduced tendency to pregnancy in the future and postpartum depression [31].

As this proposal will be performed in three stages, it has several strong points. It will fill the important knowledge gaps in the support and participation of women in labor and delivery. Therefore, expectedly it would have important clinical outcomes. Since administration of Remifentanyl for analgesia is growing both in Iran and worldwide, but the experience of delivery with Remifentanyl and its comparison with C-section have not been done quantitatively and qualitatively either in Iran or other countries, assessment

of women's experience in comparison of neonatal plus maternal outcomes in both types of analgesia method of delivery using a mixed approach will help in better understanding the issue. The obtained results can be used by health policymakers and planners for enhancing the quality of midwifery care.

Abbreviations

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

Declarations

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:

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Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests

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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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Figures

Figure 1

Study visual diagram