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

Rana Dousti[1], Sevil Hakimi[1], Hojjat Pourfathi[2], Roghaiyeh Nourizadeh[1], Niloufar Sattarzadeh[1]*

Abstract

Objectives: Women's experience during childbirth can affect various aspects (psychological and physical), which has not yet been done accurately. The current study aimed to compare experiences of parturient women with remifentanil analgesia and elective cesarean section (C-section) and provide improver strategies for women living in Tabriz, Iran.

Methods: This is a mixed-method study with an explanatory sequential approach. The first stage is quantitative and longitudinal. Participants will be divided into two groups of elective C-sections and parturient women who receive remifentanil. They will be matched concerning social class, type of provider, and birth rank. In the first stage, data will be collected using a socio-demographic questionnaire, Edinburgh's Depression during pregnancy questionnaire, Labor Agentry Scale, and midwifery-neonatal outcomes checklist within 24 hours after delivery. Participants will be followed up to 30 days after delivery to complete the Edinburgh Postpartum Depression questionnaire. The second stage is a qualitative study to explain the perceptions of parturient women who had either elective C-section or painless delivery (using remifentanil), including factors related to labor experiences. In the third stage, a mixed study will be performed to provide strategies for improving labor experiences.

Discussion: Women's experiences during cesarean section can have different effects on maternal and neonatal outcomes; Following the use of two methods of continuous analgesia with remifentanil and spinal anesthesia and analgesia caused by these methods in cesarean section, women's experiences may be different; The protocol presented in this study is a clinical guide to present this important issue (experiences of women during cesarean section looking for an appropriate method of analgesia).

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Keywords: Remifentanil, Cesarean section, Experience, Birth.

Introduction

Investigating mothers' experiences of childbirth helps caregivers better understand their needs and expectations and design effective interventions based on the identified needs to improve their satisfaction (1). On the other hand, a negative childbirth experience can affect breastfeeding. It may cause depression, post-traumatic stress disease (PTSD) (2), the decision for future pregnancy, and the type of delivery in the next pregnancy (3-5). 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" (6). 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 mothers and families, which some women experience after giving birth (6). The type of delivery is a risk factor for developing postpartum depression (7). Studies have reported conflicting results (1,8). Ukpong and Owolabi reported that C-section is associated with an increased risk of developing postpartum depression (9).

One of Iran's main policies to decline the effects 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 previous delivery experience. Having a negative experience and dissatisfaction with previous pregnancies decline the likelihood of future pregnancies (9). Although painless deliveries are expanding, we could not find a study comparing women's childbirth experience with remifentanil analgesia and elective C-section, either in Iran or other countries, and either quantitative or qualitative. Meanwhile, analgesics with remifentanil are on the rise in Iran and different parts of the world (10).

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

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[1]Department of Midwifery, Nursing and Midwifery Facility, Tabriz University of Medical Sciences, Tabriz, Iran. [2]Facility of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran.
***Corresponding Author:** Niloufar Sattarzadeh, Email: sattarzadehn@gmail.com

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 better understand the research subject, compared to when each of these approaches is used separately (11,12). Since postpartum depression can affect postpartum as well as postpartum maternal health, it is necessary to find ways to identify it so that the problem can be solved based on those strategies; Because depression is one of the factors affecting the bad experience of childbirth in women and can have different consequences; On the other hand, the amount of pain during childbirth also affects the experience of childbirth, which is related to the type of analgesia during childbirth. According to what was said, 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 to provide improved strategies. In this study, we will use a sequential explanatory approach to increase the accuracy and quality of data and to use the findings to evaluate different methods of delivery (Figure 1).

The main goal of this study is to compare the experiences of parturient women with remifentanil analgesia and elective C-section and provide improver strategies.

Materials and Methods

Study Design

This is a mixed-method study with an explanatory sequential approach done in three stages (Figure 2). At this stage, related articles were first identified; Then the text of the articles were read carefully and along with it, the experiences of several professors who were skilled in this field were used and finally the protocol was designed. In general, it can be said that a protocol design was done in addition to using sufficient scientific resources and experience.

First Stage

The first stage was quantitative and longitudinal and intended to estimate the mean score of labor experience and postpartum depression score and factors that influence these scores in parturient women with Remifentanil analgesia and elective C-section in the city private hospitals of Tabriz.

a. Participants

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

b. Sample Size

The sample size was determined using the study by Barber KE and colleagues (13), and based on the childbirth experience, the following variables were considered: m1 (SD1) = 49.1 (10.1), m2 (SD2) = 50 (8.7), α=0.05, and power=%95. The sample size was calculated as 63 subjects in each group. However, considering an attrition rate of 10%, the sample size was increased to 140 (70 in each group).

c. *Sampling*

After obtaining the ethics committee approval, the rate of vaginal rate in private hospitals was obtained. 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

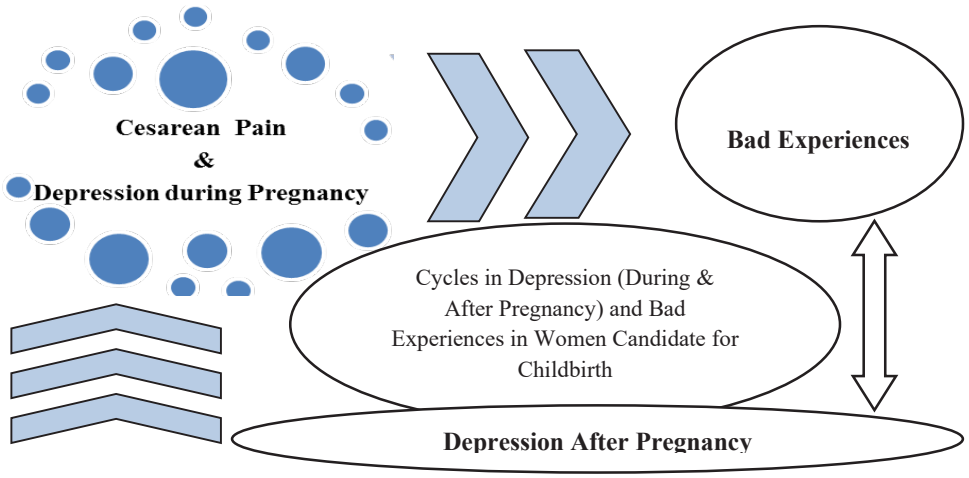

Figure 1. The Cycle of Factors Affecting the Bad Experience of Childbirth.

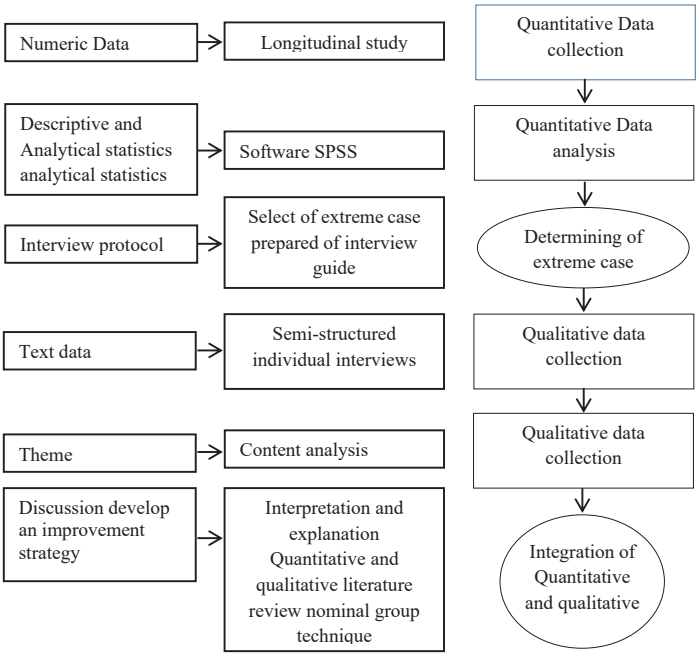

Figure 2. Study Visual Diagram.

participants. The objectives and method of the study will be fully explained to eligible participants, and, if agreeing, informed written consent will be obtained. Participants unable to fill out the questionnaire will be interviewed verbally. We will use their fingerprint for the informed written consent form. Participants will be ensured of the confidentiality of the information. Besides, they will be ensured that the research team will not mention their names. The socio-demographic and Edinburgh Postnatal Depression Scale (EPDS) questionnaires will be filled using an in-person meeting. The participants will be followed up to fill out the labor experience questionnaire and midwifery-neonatal outcomes checklist 24 hours after delivery. In the second stage of follow-up (one month after delivery during the third periodical visit to health centers), the researcher will complete the postpartum depression questionnaire for the second time (Figure 3).

d. Inclusion and Exclusion Criteria

Women in 37-42 weeks of gestational age, living in Tabriz, having their first or second delivery, women with Remifentanil Analgesia and elective C-section were included. Women with multiple pregnancies, 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 >12 in EPDS questionnaire were excluded.

e. Scales and Data Collection

Socio-demographic questionnaire: It contains age, age of

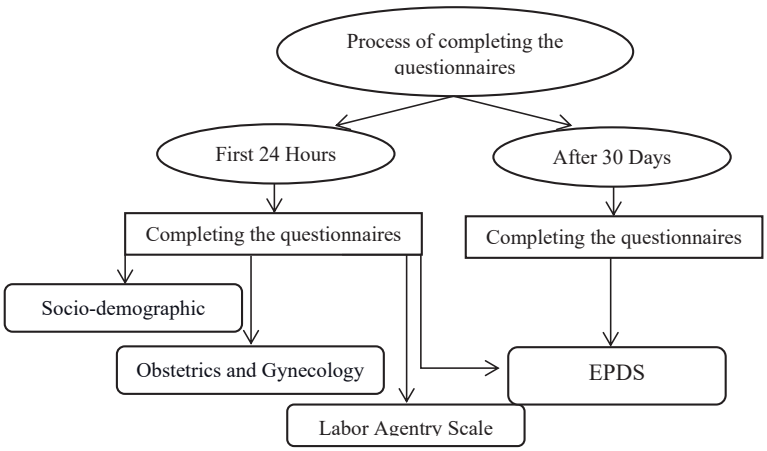

Figure 3. First Step Visual Diagram.

spouse, education level, socioeconomic status, etc. This questionnaire should be completed on the admission day.
Obstetrics and Gynecology Questionnaire: It contains 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 (14): 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, 4). Also, there is a 7-point-Likert scale, ranging from high to low intensity (3, 5-10). 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 (15). This questionnaire is psychometrically evaluated in Iran (16).
Labor Agentry Scale: 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. Madady et al (17) have confirmed its validity and reliability. They reported a content validity index of 0.91 and a content validity ratio of 0.98.

f. Data Analysis

Data will be analyzed using SPSS version 24 (IBM Corp, Armonk, New York). 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 (25-75 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 socio-demographic and midwifery characteristics and basic depression score, will be used to compare depression and childbirth experience among the study groups.

Second Stage

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

a. 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.

b. 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.

c. 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 (18). Content analysis is more than just extracting objective contents from textual data. In this way, themes (hidden patterns) can be extracted from collected data (19). The core of the qualitative content analysis is the creation of classes, a group of contents that have commonalities. 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. The notes obtained from interviews are classified and themes (20).

The qualitative content analysis method contains three conventional, directed or summative approaches. 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. The created classes are used to organize and categorize codes into meaningful categories (Figure 4). Ideally, the number of codes ranges from 10-15 (21).

Third Stage

Methodology

According to the main goal of this study (i.e., developing strategies to improve 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 crucial for health policymakers.

In total, eight multidisciplinary experts in the field of health will participate in the present study, including university professors, researchers, and policymakers

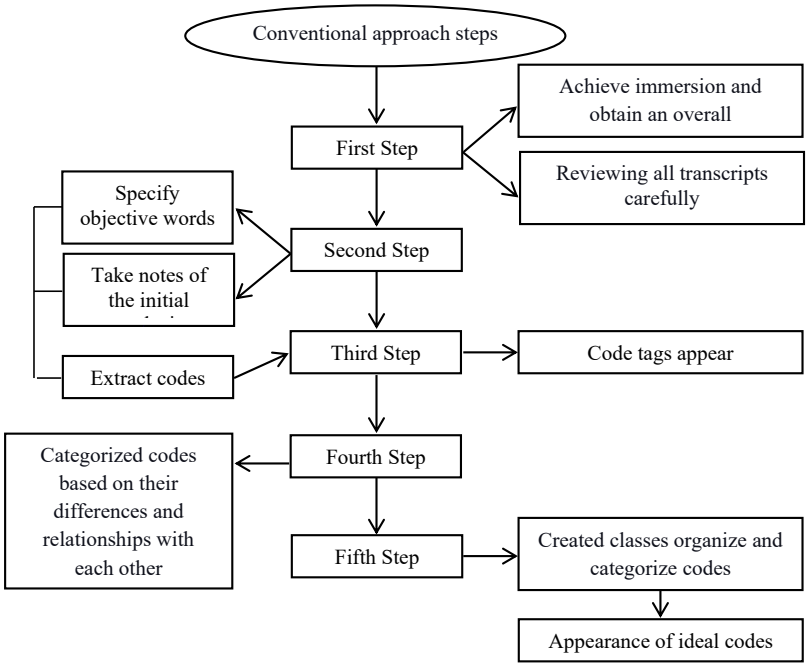

Figure 4. Second Step Visual Diagram.

educated in obstetrics and gynecology, health promotion, reproductive health, psychiatry, anesthesiologist, sociologist, and anthropologist of health and medicine. A policymaker in reproductive health will also participate in the present study. Participants will be invited based on their information and experience in reproductive health. All members of the research team will present at meetings. In addition, the researcher will run the meeting as the facilitator.

A week before the nominal group meeting, preparations will be made. 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, the nominal group method phases will be as follows (Figure 5).

Step 1: Opening the Session

In this step, after acknowledging all participants for their presence, the meeting steps 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 min to write their ideas. This step will take place in silence, and there will be no discussion among the group members.

Step 3: Round-Robin Recording of Ideas

At this step, the members ideas 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

All ideas will be discussed and clarified at this stage, 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, and 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 is worth noting that combining the 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

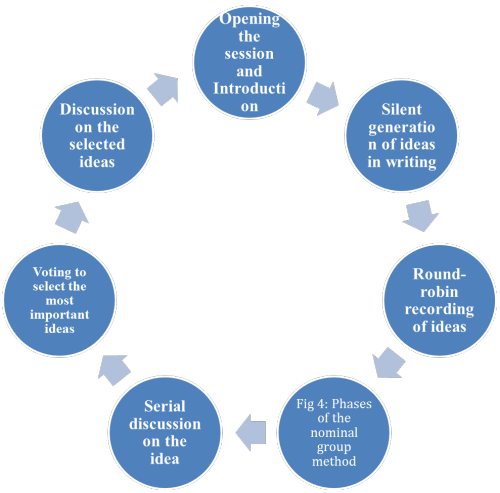

Figure 5. Phases of the Nominal Group Method.

and reliability of the results were improved by using predetermined criteria for selecting participants and employing a detailed predetermined question (22, 23).

Discussion

Women's childbirth experience depends on various social, environmental, and organizational factors and 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 (24). The World Health Organization (WHO) stated that receiving support from loved ones during labor and delivery can positively influence the childbirth experience (11). According to a systematic review study, continuous support during labor is the most important factor affecting the experience of childbirth. It is important to pay attention to the mothers needs 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; the results of this systematic review study are consistent with the results of our study (25).

Childbirth is one of the most challenging psychological events in a women's life, 10-34% of mothers have faced negative birth experiences (26). Negative childbirth experience is associated with PTSD, disruption of interpersonal relations, inefficiency in maternal-neonatal relations (27), reduction in exclusive breastfeeding (28), improper use of maternity and neonatal care services (29), and fear of childbirth and increased tendency to elective C-section in future pregnancies (3). 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; In this regard, the results of our study are in line with the results of the studies and the contents mentioned, and it seems that the design of this protocol can reduce the psychological damage during childbirth. Memories related to childbirth last for several years in the mother's mind (5). A negative childbirth experience is associated with low quality of life, the persistence of pain in the mind, and PTSD. Besides, it may lead to a decreased tendency to pregnancy in the future and postpartum depression (29,30).

The results of the review study are the same as the results of our study so the results indicate that most women with a history of remifentanil during labor have satisfactory childbirth compared to other opioids. However, compared to those who received combined spinal and epidural anesthesia, the remifentanil group was less satisfied (6).

Despite the positive effects of physiologic delivery training intended to reduce anxiety and increase the sense of pain control, conducted studies have reported conflicting results. These training were not successful in reducing C-section rates (6,9). Review study 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 childbirth experience. Meanwhile, several factors can influence women's satisfaction and experience, including the applied painless method for labor (7).

This proposal, which has three stages, has several strengths. This will fill important knowledge gaps in reducing the fear of childbirth and having painless childbirth. We will develop strategies for improving the childbirth experience by comprehensively reviewing the literature and based on the findings of quantitative and qualitative stages. Experts, and pundits can use these strategies. 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-sections have no scientific reason except the fear of labor pain. It is 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, with a mixed approach, the current is designed to achieve a deeper understanding by combining various approaches and methods.

Authors' Contribution

NS and RD designed the study and conducted the research. SH, RN and HP participated in implementation and analysis strategy. Further, all authors approved the final manuscript and take responsibility for the integrity of the data.

Conflict of Interests

The authors declare that they have no competing interests.

Ethical Issues

The current study is approved by the Ethics Committee of the Tabriz University of Medical Sciences, Tabriz, Iran (Code: IR.TBZMED.REC.1399.521- Pazhoohan Code: 65454). 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 receive. At both quantitative and qualitative stages, informed

written consent will be obtained from participants.

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