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Effect of Virtual Reality Camera on Stress and Anxiety and Maternal and Neonatal Outcomes During Cesarean Section Under Spinal Anesthesia, the Protocol of a Randomized Clinical Trial Study

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Abstract

Background: Childbirth and delivery are among the most joyful and stressful parts of a woman's life and could considerably influence the mother and her child's health. Helping mothers reduce their stress and anxiety about this procedure, especially during cesarean sections, may lead to better outcomes.
Objectives: In this study, virtual reality (VR) technology will be applied as a potential modality to reduce maternal anxiety and stress during cesarean sections and improve maternal and/or neonatal outcomes.
Methods: In this randomized clinical trial study, VR headsets, as a novel technology, will use to reduce maternal anxiety and stress during cesarean section by spinal anesthesia. Outcomes such as maternal stress, anxiety, pain, postpartum hemorrhage, and neonatal outcomes such as Apgar score and respiratory distress will be evaluated and compared with a control group.
Conclusions: In conclusion, our study wants to provide an initial insight into the advantages of using VR technology during cesarean section, and we will be able to understand if VR could improve the quality of surgeries.

Keywords: Virtual Reality, Cesarean Section, Anxiety, Pregnancy

1. Background

Virtual reality (VR) is a technology that provides computer-generated three-dimensional multimedia sensory environments for users in real-time to explore and manipulate. VR technology which is used in various branches, but mostly in the game and movie industry, connects humans and machines through different techniques such as computer graphics, image processing, pattern recognition, artificial intelligence, network, and sound systems to produce computer stimuli and interaction and then by using sensory reactions including virtual, auditory and tactile sensation and make the user feel he or she is in the real situation (1, 2).

Recently, the user's behavior attracted the attention of researchers in the field of medicine and health care in VR. Most applications of this technology include medicine simulation telemedicine, medicine and health services education, pain control, illustration for operation, rehabilitation for stroke, treatment of pain, and trauma (3). VR can also be used for different goals in pregnancy. VR imaging methods can evaluate fetal growth and situation. Indeed, healthcare providers can be taught VR techniques for labor sonography and laparoscopy surgery (4, 5).

Like pregnancy, delivering a baby is also the moment of the most joy and stress in a woman's life. VR also facilitates delivery by educating them to manage the pain during labor. Normally, the mother's blood pressure and heart rate increase during labor; if the mother has stress or pain, increasing the uterus perfusion will intensify the blood pressure and heart rate increase (6, 7). In cases of cesarean section, the mother's stress from the operating room is the fear of pain from the surgery and possible complications for the baby. Indeed, spinal anesthesia may be painful and anxiety-provoking for her. In this era, VR can provide a simulation environment and distract patients'

concentration from the pain (8). On the other hand, VR provides pictures from the virtual environment like real nature. VR also helps to decrease the concentration of women from their surroundings and calms them down (9, 10).

Most of the studies confirm the positive effect of VR on women who undergo a cesarean section (11, 12), but another trial has shown that VR couldn't decrease stress (13). However, this could be due to differences between the two groups' base stress score, level of education, history of psychological disorders, and emergency cesarean section. Based on a study done in 2019, the stress level in patients who experienced an emergency cesarean section was reduced by using VR. Since maternal stress and anxiety can increase the risk of adverse events, including preeclampsia, hypertension, and heart diseases, it is essential to reduce stress during labor and pregnancy (14).

Although VR technology is novel in Iran, few studies have determined VR's effect, so more clinical studies are needed.

2. Objectives

This study aims to evaluate the effect of virtual reality cameras on maternal stress and anxiety as well as maternal and neonatal outcomes during cesarean section by spinal anesthesia to investigate if, by utilizing VR technology, healthcare providers could reduce the adverse effects of cesarean section surgeries.

3. Methods

3.1. Study Design

This randomized clinical trial study contains a case (VR) and a control (non-VR) group. The study population is termed pregnant women candidates for cesarean section in an academic center from March to September 2023. This protocol was designed using SPRIT criteria (15). This study was registered at the Tehran University of Medical Science

3.2. Eligibility Criteria

Inclusion criteria include term pregnant women between 18- and 45 years, candidates for elective cesarean section with spinal anesthesia, and agree with the study statement. The exclusion criteria include patients with a history or at risk of seizures, medical conditions such as chronic hypertension, and a past medical history of any psychological condition such as anxiety. Also, patients exposed to any unforeseen operating room conditions requiring general anesthesia are excluded from the study. The patients will be free to take off their headsets whenever they decide. Before their recruitment, the research team should ask all the patients about their preferences and fears regarding the virtual reality environment: for example, water phobia and ocean 360° reality or a history of travel-disease sensitivity to avoid dizziness due to 360° and moving environment. Patients who are afraid or have a positive history of travel-disease sensitivity should be excluded.

3.3. Criteria for Discontinuing or Modifying Allocated Interventions

The study will be discontinued if more than half of the patients have a headache, vertigo, or any condition in which the patient couldn't complete the study. In this unit, routine anesthesia and surgical procedures are performed without using VR.

3.4. Data Collection

Characteristics of the patient, including demographic data such as age, body mass index (BMI), education, and socioeconomic status, as well as obstetrics information including gestational age, gravidity/parity, past medical and previous experience of surgery and anesthesia type, will be entered into the researcher checklist. All the data will be collected after the patients are enrolled. The hemodynamic statement of patients, such as systolic blood pressure (SBP), diastolic blood pressure (DBP), and SPO2, will be monitored.

3.5. Intervention and Setting Up the VR

Patients will be divided into two groups randomly. Before the intervention, the research team will describe devices and teach the study population how to use headsets. The occasions, including hardware needs like touch sensors and software, need designing of a virtual reality environment. We chose the selected video of nature, including the ocean. A 360-degree video will be uploaded, giving the case a 360-degree view. When watching these videos, she feels real, even though she knows that it is an illusion.

3.6. Outcomes

Primary outcomes include hemodynamic statements of patients before and after surgery in both the intervention and control groups and then comparing them. Pain, postpartum hemorrhage, maternal stress, anxiety level, and neonatal outcomes such as respiratory distress and Apgar score before and after the intervention will be compared with the control group.

3.7. Instruments

(1) A visual analog scale (VAS) will be used to determine the pain. 0 point serves as painless to 10 points as extreme pain.

(2) Depression Anxiety and Stress Scale-21 Item (DASS-21) will be used to evaluate anxiety and stress. This questionnaire is a self-report inventory composed of three subscales: Depression (DASS-D), Anxiety (DASS-A), and Stress (DASS-S) (16). The questions are composed of three 7-item subscales, with each item scored on a Likert scale, ranging from 0 (did not apply to me at all) to 3 (applied to me very much, or most of the time). This questionnaire is validated in Persian with adequate psychometric properties in Iranian populations (17). Patients will answer these questions within 24 hours after surgery.

3.8. Recruitment and Allocation

The participants will be allocated equally and randomly to the case or control group. Randomization will be performed equally by size 2 blocking. Dual blocks will first be created from codes A (case) and B (control) which will be assigned to the participants according to the sequence.

3.9. Ethical Consideration and Confidentiality

The ethical board of the Tehran University of Medical Sciences will accept the study protocol. This study will be conducted according to the Helsinki Statement. The study statement will be described for patients, and participating in the study will be voluntary. All participants have read and signed the written informed consent. However, patients' information will be private.

3.10. Statistical Methods for Primary and Secondary Outcomes

The number (%) will be used for categorical variables, and the mean (standard deviation) will be presented for continuous variables. The Chi-square test and independent t-test will assess the effect of VR on each outcome. Also, we use IBM SPSS software version 20 for data analysis. The level of statistical significance was set at $P < 0.05$.

4. Discussion

This study aims to determine the effects of using VR technology on maternal outcomes such as PPH, VAS, and stress and anxiety levels during and after cesarean section and also evaluate whether using VR technology can reduce the adverse effects of spinal anesthesia.

As we know, women who undergo cesarean section experience more stress and anxiety, less confidence, and less oxytocin level and are likely to be at risk of lower mental health after delivery (18). Indeed, spinal anesthesia during a cesarean section could have side effects such as hypotension and nausea (19). Therefore, finding ways to control symptoms will be very helpful.

Using VR technology can reduce pain and stress before and during labor by distracting patients; in the study that was done by Momenyan et al., using VR significantly decreased pain and anxiety in the first stage of labor, and also the Apgar score was higher in the women who used VR (20). Also, VR was used to decrease the intraoperative sedative dose, leading to fewer postoperative side effects and oversedation (21) in a study by Alaterre et al. (22), the immediate postoperative satisfaction score was significantly higher, and the anxiety level was lower in the VR group compared to the control group. Also, the VR group experienced a reduction in the occurrence of intraoperative hemodynamic changes and tachycardia.

4.1. Conclusions

In conclusion, our study wants to provide an initial insight into the advantages of using VR technology during cesarean section, and we will be able to understand if VR can improve the quality of surgeries.

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Footnotes

Authors' Contribution: SH and MG: Design of the work; KJ and MR (Mohammad Moein Rezaei) and FA: Drafting and editing the manuscript; MR (Mahroo Rezaeinejad) and BM: Interpretation of data.

Conflict of Interests: The authors have no conflict of interest.

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