

Immersive Virtual Reality Improves Labor and Delivery Experience for Women: A Randomized Controlled Trial

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Research Article

Keywords: Labor, Immersive Virtual Reality, Pain, Non-pharmacologic Treatment, Anxiety, Depression

Posted Date: October 13th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-898920/v1>

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Abstract

Objective: To evaluate the effectiveness of immersive Virtual Reality (VR) in laboring women on patient satisfaction as a distractive tool and pain relief.

Methods: Randomized, controlled clinical trial with 42 laboring women allocated to VR intervention and control groups. Among the VR group, patient satisfaction with the use of VR was assessed by a Virtual Reality Satisfaction Survey and questioning whether they would choose VR in future labor. As a primary outcome patient satisfaction scores regarding the overall labor and delivery experience were compared between the two groups. A secondary outcome was pain assessed by a visual pain rating scale in the early and active phases of labor in both groups. Psychometric information was also collected from participants in each group using Beck Anxiety Inventory and Beck Depression Inventory.

Results: We observed a high level of patient satisfaction with the use of immersive VR during labor. The survey revealed a mean satisfaction score of 89.6 ± 10.8 out of a maximum of 100. 20 out of 21 (95%) women in the VR group stated that they would like to use VR again in future labor. VR improved pain scores in early labor and contributed positively to overall labor and delivery experience. The mean pain score pre-VR was 2.6 ± 1.2 compared to 2.0 ± 1.3 , post-VR, respectively ($p < 0.01$). Anxiety and depression scores were similar in the intervention and control groups ($p = 0.103$, $p = 0.13$, respectively).

Conclusion: Immersive VR application during labor was feasible and associated with higher patient satisfaction based on our study. VR also improved pain scores in early labor before epidural placement. Immersive VR may find a place as an adjunct in Labor and Delivery Units to improve the lengthy labor experience for women. Larger studies are needed to confirm these observations.

Trial Registration: ClinicalTrials.gov: NCT05032456 / 02/09/2021

<https://clinicaltrials.gov/ct2/show/NCT05032456>

1. Introduction:

Labor is a long and painful process for women. The neuraxial blockade, which includes epidural, spinal, and combined spinal-epidural analgesia, is presently the gold standard for pain control in laboring women. [1] [2] However, improving the whole labor and delivery experience for women is more complex and requires providing individualized care including alternative treatments.

Opioid and non-opioid pharmacotherapies, patient-controlled analgesia (PCA), nitrous oxide are all used with variable success for labor pain. [3]

Acupuncture, hypnosis, yoga, hydrotherapy, massage, relaxation techniques, and transcutaneous electronic nerve stimulation (TENS) are among the adjuvant treatments provided to women in labor. [4] [5] [6] [7]

Recent literature indicates the successful use of immersive virtual reality (VR) for a variety of painful medical procedures.[8][9][10][11][12][13] Via wearing the VR goggles the user has the illusion of going inside the 3D computer-generated world and visiting novel environments. Immersive VR is hypothesized to reduce pain through distraction, a non-pharmacologic attentional mechanism. The user's brain is preoccupied with the flood of information presented by the virtual environment restricting the mind from processing pain signals. [14]

We hypothesized that laboring women find immersive VR as a beneficial tool for their overall labor and delivery experience. We randomly assigned women in labor admitted to our Labor and Delivery floor to a VR group or a control group.

2. Materials And Methods :

2.1. Study Design

This was a randomized, controlled, single-center clinical trial in which we enrolled 42 women admitted during labor. We randomized these women to immersive virtual reality (VR) or control group following their approval and written consent. The study was approved by the Institutional Ethics Committee of Acibadem Mehmet Ali Aydinlar University (IRB protocol no: 2020-18/07) and registered with clinicaltrials.gov (NCT05032456 / 02/09/2021). The primary objective of this study was to assess whether immersive VR was feasible and improved patient satisfaction in laboring women. We assessed patient satisfaction among VR users and compared patient satisfaction regarding overall labor and delivery experience between the two groups. Our second objective was to assess whether VR provided pain relief in the latent or active phase of labor. We also evaluated anxiety and depression in both groups on admission as potential confounders. The study took place at Acibadem Maslak Hospital, a private hospital affiliated with Acibadem University School of Medicine in Istanbul, Turkey. Enrollment completed between November 2020 and June 2021).

2.2. Study Subjects

Participants of this study were primigravida or multigravida presenting with labor who are candidates for vaginal delivery with no known risk factors. The inclusion criteria were women between 18-42 years of age at 37-41 weeks gestation with a singleton pregnancy, vertex presentation, no history of chronic medical conditions, absence of pregnancy complications, and admission with documented labor by cervical exam and regular uterine contractions. Women with a diagnosis of migraine, headache, dizziness, motion sickness, epilepsy, psychiatric disorders, visual or auditory disabilities, history of cesarean section were excluded.

2.2.1. VR Group

We used Oculus Quest All-in-one VR Gaming Headset (128 GB) VR system. Before the intervention, the authors introduced the equipment and instructed study participants on how to wear and activate the

headsets. Anxiety and depression scales were also applied on admission. The laboring women who enrolled in the VR group first wore the headsets in early labor (Cervical dilation 3 cm) for 20 minutes. The patients were offered to choose among several virtual environments including orange sunset, green meadows, black beginning, red savannah, blue deep, blue moon, blue ocean, white winter, and red fall (Figure 1). Cards printed out from the screenshots of the Nature Treks application representing these novel immersion options were provided to the patients to help them pick up their preferred environment in advance. The second implementation of VR headsets was after the epidural analgesia in the active phase of labor for another 20 minutes (Cervical dilation 6-7cm). After the second intervention, the "Virtual Reality Satisfaction Survey" was applied by the authors. Patients were asked to fill out a visual pain rating scale right before and after the VR use in early and active labor.[15]

2.2.2. Control Group

For participants randomized to the control group, VR headsets were not used and our standard of care in laboring women was followed. Anxiety and depression scales were applied to each subject on admission. Participants in this group filled out a visual pain rating scale both in the latent and active phase of labor.

2.3. Clinical Measures

To evaluate the effectiveness of immersive VR in laboring women, we evaluated patient satisfaction with the use of VR among the intervention group. Patient satisfaction with overall labor and delivery experience and pain scores were compared between the intervention and control groups.

Patient satisfaction with the use of VR was assessed by a "Virtual Reality Satisfaction Survey", a 10 questions survey prepared by our team: 0 being the lowest and 100 being the highest possible VR satisfaction score. We also asked these women whether they would like to use VR in future labor. Patient satisfaction with overall labor and delivery experience was assessed using a Numeric Rating Scale (NRS). All discharged women were called a week following discharge and asked to rate their overall childbirth experience on a scale from 0 to 10. Zero indicates the most negative experience possible and 10 indicates the highest satisfaction possible. We classified a score of 8 to 10 as high satisfaction. Pain scores both in early and active labor in each group were assessed using Wong-Baker Faces Pain Rating Scale. [18] The scale shows a series of 6 faces ranging from a happy face at 0, or "no hurt", to a crying face at 5, which represents "hurts like the worst pain imaginable (Figure 2).

Anxiety levels of study participants were assessed with Beck Anxiety Inventory (BAI). [16] This inventory consists of 21 items, each scored from 0 to 3. This is a self-report questionnaire measuring somatic and cognitive parts of anxiety. The total score is calculated by finding the sum of 21 items. A score of 0 to 7 indicates minimal anxiety, 8 to 15 mild anxiety, 16 to 25 moderate anxiety, and 30 to 63 is associated with severe anxiety.

For the assessment of depression in each group, Beck Depression Inventory was used. It consists of 21 items which is a multiple-choice test and give a score ranging from 0 to 63. Each answer is scored on a scale value of 0-3. Measures of 0–9 indicate that a person is not depressed, 10–18 indicates mild-

moderate depression, 19–29 indicates moderate-severe depression and 30–63 indicates severe depression. This self-rated test estimates the signs of depression such as pessimism, feeling of failure, self-dissatisfaction, punishment, crying, insomnia. [17][18]

2.4. Statistical Methods

2.4.1. Sample Size Calculation

A priori power analysis was performed to estimate the sample size with a power (1- β) of 80%, a significance (α) of 0.05 and an allocation ratio of 1. We assumed a neutral satisfaction score of 50 out of 100 (SD=12.5) for the control group and hypothesized 25% increase in satisfaction scores with the use of VR. A sample size of 17 subjects per group were computed to be required to observe this difference. For this analysis *G*Power* software was used. For potential drop outs we decided to enroll 21 subjects in each group. Subjects were randomized to an intervention (VR) group (n=21) or a control group (n=21) using a random number generator (www.random.org).

2.4.2. Data Analysis

Statistical analyses were done using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. Descriptive statistics were presented as mean score, standard deviation and absolute frequency. To compare the mean overall labor and delivery satisfaction scores as well as anxiety and depression scores between the two groups, independent t-test was used. We used paired samples t-test for the comparison of pain scores before and after the VR experience in early and active labor. A p-value of less than 0.05 was considered statistically significant.

3. Results :

Of the 130 women admitted in labor, 68 were eligible for inclusion in the study, 42 of them agreed to participate in this study (*Figure 3*). Characteristics of laboring women randomized to either the immersive VR or the control group are shown in Table 1. There was no significant difference between the two groups in terms of these baseline characteristics.

Table 1
Characteristics of the Study Subjects

| | VR GROUP (n=21) | CONTROL GROUP (n=21) |
|--------------------------------------|--------------------|-------------------------|
| Age, Mean \pm SD | 31.0 \pm 2.6 | 31.8 \pm 3.6 |
| Gestational age, Mean \pm SD | 39.5 \pm 0.6 | 39.0 \pm 1.0 |
| Body Mass Index (BDI), Mean \pm SD | 26.2 \pm 2.7 | 26.7 \pm 3.1 |
| Parity | | |
| Primiparous (n) (%) | 18(86%) | 17(81%) |
| Multiparous (n) (%) | 3(14%) | 4(19%) |
| Delivery Type | | |
| Vaginal Delivery (n) (%) | 18(86%) | 18(86%) |
| Cesarean Section (n) (%) | 3(14%) | 3(14%) |

Vast majority of women in the VR group found their VR experience very pleasant reflected by the Virtual Reality satisfaction survey. The survey revealed a mean satisfaction score of 89.6 ± 10.8 out of a maximum of 100. 20 out of 21 (95%) women in the VR group stated that they would like to use VR again in future labor.

VR intervention improved pain scores in early labor before epidural placement. The mean pain score pre-VR was 2.6 ± 1.2 compared to 2.0 ± 1.3 , post-VR, respectively ($p < 0.01$). Following epidural analgesia pain scores were significantly lower with a mean pain score of 0.8 ± 0.5 which remained unchanged post-VR.

One week following discharge, we conducted a telephone survey where we found a significant difference when patient satisfaction with overall labor and delivery experience was questioned in the VR and the control groups. The NRS score of women in the VR group was 8.8 ± 1.1 compared to 7.9 ± 1.6 in the control group, respectively ($p = 0.04$).

Beck Anxiety Inventory revealed similar anxiety scores in the VR (11.2 ± 7.5) and control group (7.5 ± 6.7), respectively ($p = 0.103$). Beck Depression Inventory also revealed similar depression scores in the VR (7.6 ± 5.8) and control group (5.0 ± 5.0), respectively ($p = 0.13$). Women in the VR group tolerated VR application very well. No significant adverse events were observed requiring exclusion from the study.

4. Discussion :

We found that the use of immersive VR in laboring women was feasible and associated with a high level of patient satisfaction as a distractive tool. There is very limited data regarding the use of VR in laboring women. An earlier study evaluated VR use during episiotomy repair and reported less anxiety in the

intervention group.[19] Two recent studies reported reduced labor pain and anxiety with the use of VR [20]. Kist et al showed that VR provided anxiolysis to laboring women undergoing epidural placement [21]. In our study, we also noticed an improvement in pain scores following the use of VR in early labor before epidural placement. Epidural placement afterwards obviously provided substantial pain relief as evidenced by dramatically decreased pain scores in both groups. It is important to clarify that we did not test VR as a substitute for epidural analgesia. Laboring women both in the intervention and control groups received epidural analgesia at their request as part of our standard of care. We assessed whether VR might be used as an adjunct to improve the labor and delivery experience of women. Our awareness regarding the importance of a positive childbirth experience and its impact on women's physical, psychological and social well-being has gradually increased [22] [23] [24]. In addition to ensuring maternal and neonatal health and safety, improving patient satisfaction during labor and delivery has become an integral part of high-quality care as also underscored by WHO.[25]

The amount of support from caregivers and a quality caregiver-patient relationship is paramount for patient satisfaction during childbirth [26]. Accordingly, many Labor and Delivery units provide one on one nursing support for laboring women if possible. Most laboring women want to be involved in care decisions and demand their red lines to be respected. Attendance to antenatal classes and having birth plans are encouraged and increase the odds of a positive childbirth experience [27].

Since labor is associated with severe pain according to most women, pain control is very important to improve patient satisfaction [28] [29]. Currently, epidural analgesia is considered the gold standard in labor analgesia, providing the most effective pain relief during childbirth [30] [31] On the other hand many women with healthy pregnancies want to minimize medical interventions and seek non-pharmacological ways to cope with labor pain. Besides they want to be relaxed yet remain active during labor. Many Labor and Delivery units are equipped to provide warm showers, birth ball exercises to those in labor. Warm showers in labor were associated with pain reduction and contributed to a positive overall experience [32]. Birth ball exercises also provided significant improvements in childbirth self-efficacy and pain [33]. Some units work with professional therapists and offer massage therapies during labor. Massage therapy during labor was associated with pain relief and decreased anxiety as well as shorter labor duration [34].

Fear of childbirth is common which leads to increasing rates of cesarean on maternal request[35] and contributes to already high cesarean rates in countries like Turkey [36]. Considering the fact that cesarean rates have remained high in our centers with a 24-hour epidural analgesia availability, it is certain that we need to improve overall childbirth experience beyond pain relief. Our findings of high patient satisfaction with the VR use in labor along with routine epidural placement on demand further support this point. We need to present several options to laboring women to choose from such as warm shower, birth ball exercises, yoga, massage, etc possibly in an alternating fashion. Our study suggested that immersive VR might also be a valuable tool to distract and potentially entertain women during long labor hours. VR may especially be instrumental during intermittent fetal monitoring episodes when most of the above-mentioned activities are not feasible.

Although randomization and strict adherence to the standard of care in both groups of laboring women are strengths of our study, it has several limitations as well. The numbers are relatively small and obviously larger studies are needed to support our findings. It is also worth mentioning that this study was done at a single upscale health center serving an affluent cohort potentially biased towards newer technology such as VR.

5. Conclusion:

Based on the results of this preliminary study, immersive VR is feasible in laboring women and may improve pain scores likely through distraction in latent phase of labor prior to epidural placement. VR might also improve patient satisfaction, an important indicator for the quality of care in childbirth.

Abbreviations

Virtual Reality : VR

Patient-Controlled Analgesia : PCA

Numerical Rating Scale : NRS

Beck Anxiety Inventory : BAI

Beck Depression Inventory: BDI

World Health Organisation : WHO

Declarations

1. Ethics approval and consent to participate

This study was approved by the Institutional Ethics Committee of Acibadem Mehmet Ali Aydinlar University (IRB protocol no: 2020-18/07) and registered with clinicaltrials.gov (NCT05032456).

The date of disclosure of study information and trial start was 02/09/2021. The objectives, methods, and other details of this study were explained to the participants. Written informed consent was obtained before participation in this study. All methods were carried out in accordance with relevant guidelines and regulations under Ethics approval and consent to participate form.

2. Consent for publication :

Not applicable.

3. Acknowledgements

We would like to thank all the laboring women who participated in this study. We would also like to thank all the staff members, nurses and midwives of the Labor and Delivery Unit at Acibadem Maslak Hospital.

4. Availability of data and materials

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

5. Funding

Not applicable.

6. Authors' Information

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7. Authors' Contributions :

GC and HMB presented the idea of a VR study to SG. SG helped them to mature the idea and finalized the study protocol, collaborated with NA and performed the computations. SG and GC performed the analysis of the results by using IBM Statitics SPSS 25 program. NA prepared and distributed information leaflets for the VR study and helped with study recruitment. HMB provided his Oculus Quest All-in-one VR Gaming headset for the study. GC and HMB introduced the Oculus Quest All-in-one VR Gaming headset and instructed study participants on how to wear and activate the headsets. HMB applied the anxiety and depression scales on admission. GC collected the data of "Virtual Reality Satisfaction Survey" and applied it. GC imported the data into excel spreadsheet with support from HMB. HMB searched possible applications of the device (Oculus Quest All-in-one VR Gaming Headset (128 GB) VR system) and helped the authors to conclude on the use of Nature Treks for laboring women. HMB took screenshots of the environments and presented them to patients to pick up their preferred environment. NA conducted a

telephone survey about patient overall satisfaction of labor and delivery experience one week following discharge. GC and NA processed the experimental data, performed the analysis, drafted the manuscript and designed the figures. NA, GC and HMB contributed to the final version of manuscript. SG supervised the project

8. Competing interests :

The authors have no competing interests to declare.

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Figures



Figure 1

Nature Treks Environments



Figure 2

Wong-Baker Faces Pain Scale

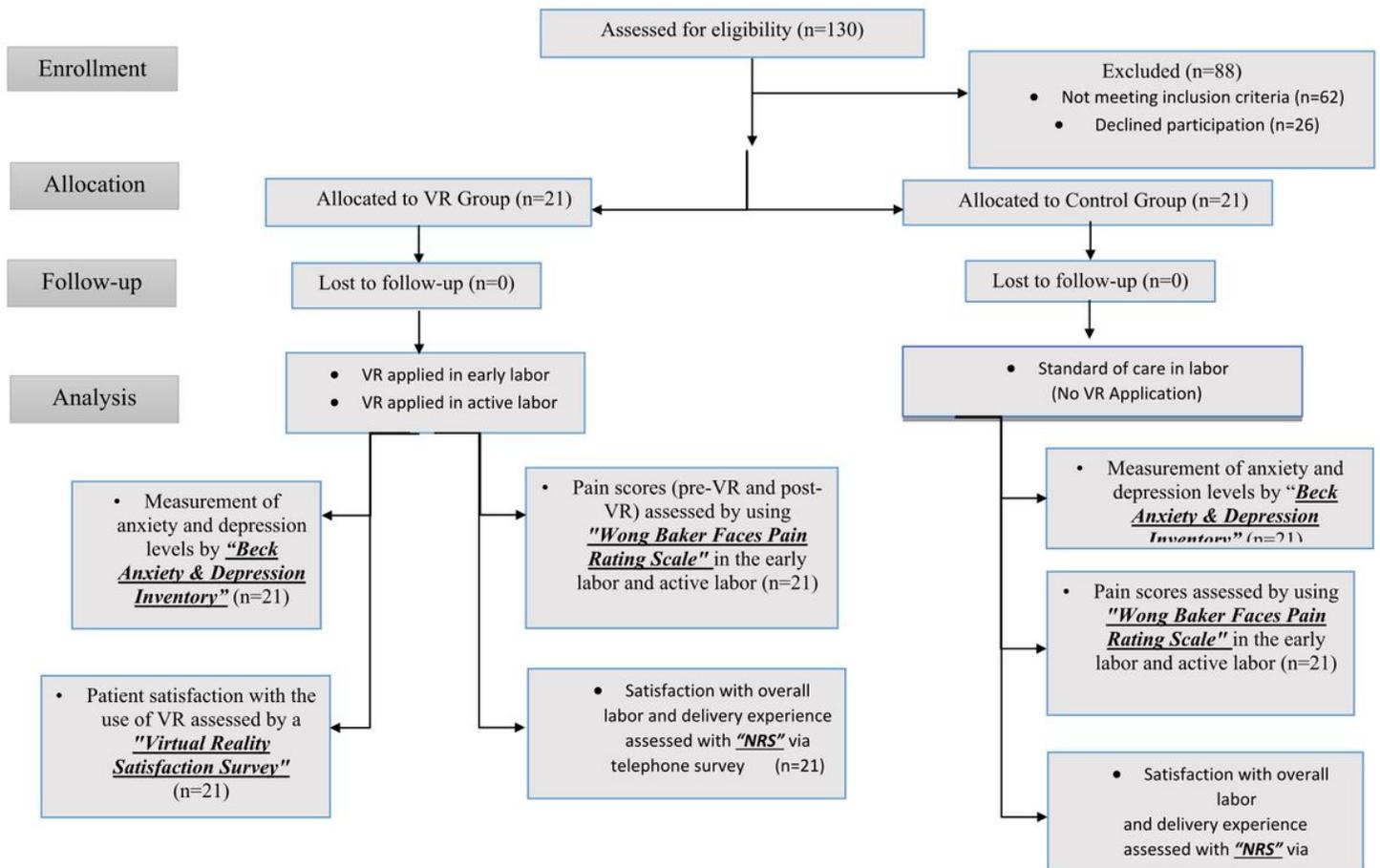


Figure 3

Flowchart of Study

Supplementary Files

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- [CONSORT2010Checklistfilled.doc](#)