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Original Research

Immersive virtual reality analgesia in un-medicated laboring women (during stage 1 and 2): a randomized controlled trial

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Introduction: In order to manage labor pain, one of the non-pharmacological approaches is immersive virtual reality (VR). This study aimed to evaluate the impact of immersive VR analgesia on labor pain, anxiety and nausea in nulliparous women. *Methods*: In this interventional study, 52 nulliparous women with a single fetus who expected vaginal delivery were randomly assigned to a VR group (n = 26) and a control group (n = 26). 4 women excluded from the study due to the desire for medical intervention for pain control. A simulated environment (containing nature scenes and sounds) was presented to the women in the VR group. Pain intensity, anxiety, and nausea were measured using a questionnaire. The two groups were compared in terms of cognitive pain, sensory pain, affective pain, anxiety, and nausea. *Results*: There was a statically significant decrease of cognitive pain during the first stage of labor in the VR intervention group compared to the control group ($P = 0.013$), whereas in the second stage of labor it was not significant ($P = 0.55$). There was no significant difference between the two groups in terms of affective pain. Also, sensory pain was significantly decreased only in the first stage of labor in the VR group compared to the control group ($P = 0.033$). Mothers in the intervention group had a lower level of anxiety compared with those in the control group ($P < 0.05$), whereas nausea was not significantly different between the two groups ($P < 0.05$) at all stages of labor. *Conclusion*: Virtual reality is an effective and feasible non-pharmacological method to reduce pain and anxiety during labor process without major side effects.

Keywords

Virtual reality; Labor pain; Nulliparous women; Randomized controlled trial

1. Introduction

Childbirth is accounted for the most memorable and unpleasant experience in a woman's life. The self-description range and intensity of this pain vary widely; a few women give birth suddenly and reported nonexistent or little pain, while at the other extreme, excruciating pain has been reported [1, 2]. The perception of labor pain could be affected by a large number of factors such as physiological and bio-behavioral processes (anxiety, fear, and confidence), the woman's position, clinical and also genetic factors [1, 3].

In order to manage the labor pain, non-pharmacological and pharmacological interventions are chosen by most women. There is a great disparity between these two analgesic modalities. The former helps the woman cope with pain and the latter aims to relieve the pain of labor [1, 3, 4]. In the United States, almost 60 percent of women with singleton pregnancy received neuraxial blockade for relieving pain during vaginal delivery [5]. Despite the fact that merely 17% of women chose un-medicated birth, 75% received some sort of non-pharmacological intervention either alone or with pharmacological methods [3]. There are substantial evidences supporting the better efficacy of drug interventions in comparison to placebos or non-drug methods to mitigate labor pain [3]. In spite of the fact that epidural analgesia is the gold standard for managing pain effectively in laboring patients, it comes at the cost of adverse effects on the newborn and mother [3]. Non-pharmacological methods bring about benefits including enhancement of mother's satisfaction with childbirth, achieving the sense of control over labor pain, and increasing the rate of breastfeeding without causing side effects [4, 6]. In a survey performed in the UK, as an example, women who decided to not use pain-relieving medications during labor reported more satisfaction than those used a pharmacological intervention [7].

One of the non-pharmacological approaches in medical procedures to attenuate acute pain is immersive virtual reality (VR). There is growing empirical evidence that supports VR's distraction effectiveness in a wide spectrum of clinical settings to control pain [8]. Although, the VR concept was initiated by Ivan Sutherland in 1960s, the VR phrase was not coined until the mid-1980s, when the first VR-based devices became available. In that time, Jaron Lanier used this phrase to refer to a user interface for real-time user interaction with a computer generated environment [9, 10]. VR has the potential to induce an illusion of presence in a simulated situation in which users would have an uncanny feeling of being exposed to the scenarios in reality [9]. Immersive VR has the ability to instantly isolate the patient from an immediate clinical setting and substituting it with a more pleasant computer-simulated environment. This can be achieved through multisensory distraction including head-mounted

display (HMD), headphones and a joystick for head tracking, music and noise reduction, and manipulation and navigation, respectively [8, 11]. In fact, VR with high degrees of immersion due to a stronger sense of presence in virtual reality [12] is considered as an effective form of distraction for achieving analgesic effects [4], compared with less immersive VR systems [12, 13], traditional videogames [14] and music alone [15]. Historically, the high cost of VR hardware and its sophisticated software made it available to few and unaffordable for widespread applications. However, as technology is on the rise in the field of high-quality screens of mobile phones, the use of high-standard HMDs has increased significantly, and VR has gained attention as an effective pain management strategy.

There has been a growing acceptance that environmental factors can play a major role in pain experience [16, 17]. The medical ward specifically maternity ward is full of patient's auditory and visual stimuli such as loud paging requests and sounds of suffering by other patients that probably exacerbate patients' pain and anxiety.

In 1984, the "biophilia" hypothesis was suggested by Wilson, which declared that humans have an inherent connection with nature, and providers could take the advantage of this bond to individual's health and pain control [18]. Also, there is a potential of reducing pain perception through viewing scenic imagery due to eliciting positive emotional responses [19]. In 1984, Ulrich [20] performed a research to compare recovery after cholecystectomy surgery. He provided a brick wall view for patient in the control group and natural landscape through hospital room windows for patients in the intervention group. He found that natural scenes improve recovery from surgery. Results of these studies support the idea that viewing nature scenes can decline blood pressure within 3 min resulting in significant recovery from stress.

Natural scenes are typically unavailable to patients in the medical ward. Regarding to this, using scenery landscapes in VR's environment could have positive influence in reducing patients' pain. Miller *et al.* examined the impact of video and music on pain and anxiety in burn patients. Seventeen patients were randomly assigned to two groups. Videos of scenic imagery and music were presented to those who were in the intervention group during wound dressing. The results showed that patients in the intervention group had lower pain intensity and anxiety [21].

The present study aimed to assess the impact of immersive VR analgesia on cognitive, affective, and sensory components of pain, anxiety, and nausea in nulliparous women experiencing un-medicated labor. Our hypothesis was that VR immersion has a significant effect in reducing feeling pain, anxiety and nausea during the first and second stage of labor.

2. Methods

This interventional study was performed on 52 women experiencing un-medicated labor referred to Shahid Rajaei Hospital in Tonekabon, Iran, in September 2019. To make the information of this clinical trial study publicly available, it was registered on irct.ir with trial ID: IRCT20181224042099N1, on June 25, 2019. Assuming that the standard deviation of the worst pain score in each group is 2 and α is 0.05, a sample size of ≥ 24 participants would detect a difference in the means between the 2 treatment groups of 1.5 point with 80% power. After taking the approval of the Ethic Committee of Tarbiat Modares University, 52 women were selected by convenience sampling. Then, they were divided into two groups of 26 people (i.e., A: intervention and B: control groups, in which samples in intervention group would experience the VR intervention whilst the ones in the control group would not). Assignment of the patients is done using permutation blocks randomization with a fixed block size 2 and permuted sequences as follows: AB and BA. Then, using the random number table (computer generated), sequence of such blocks of random numbers was generated. Finally, each patient was labeled by either A or B according to her Id number, and the random number in the sequence allocated to her.

The inclusion criteria were any healthy Iranian woman at age > 18 and < 45 years who has the ability to read and write, giving birth for the first time after 38 weeks, does not have a desire to use a pharmacologic intervention for pain control, has a low risk pregnancy without obstetric complications, and in the first stage of labor with an anticipated vaginal delivery. Exclusion criteria included high-risk pregnancy, the need to use other method of analgesia (epidural analgesia or other opioids), anomaly in fetal or placental, inability to recognize and assess the intensity of pain, hearing or vision impairment, mental disorders, seizure history, or reported predisposition for motion sickness or undesirable memory of the VR's content. After signing and giving back the informed consent describing the nature of the research and the patient's right on presentation for delivery, all eligible participants completed a demographic questionnaire included age, educational level, economic status, occupation, pregnancy weeks and history of abortion. During the study, also, one questionnaire in the first and second stage of labor was completed by the participants to assess 3 separate pain outcomes, anxiety and nausea. To measure these factors, numerical rating scale tools were used. Patients rated this self-administered rating scale based on the amount of time they spent thinking about pain (cognitive pain dimension), pain unpleasantness (affective pain dimension), worst pain intensity (sensory pain dimension), the amount of anxiety, and the amount of nausea they experienced. According to previous studies, these pain dimensions have assessed the intensity and quality of pain in a reliable way for evaluating the treatment effects [22, 23].

Prior to the intervention, the objectives, detailed of the intervention and study have been explained to the voluntary participants, and the confidentiality of their answers was assured.

Fig. 1. The VR's environment of natural scenery. A sample picture of the 360 degrees video; when the patient turns her head to the right, she would see the whole see and when she moves her head up, she will see the sky while she hears sea waves sound.

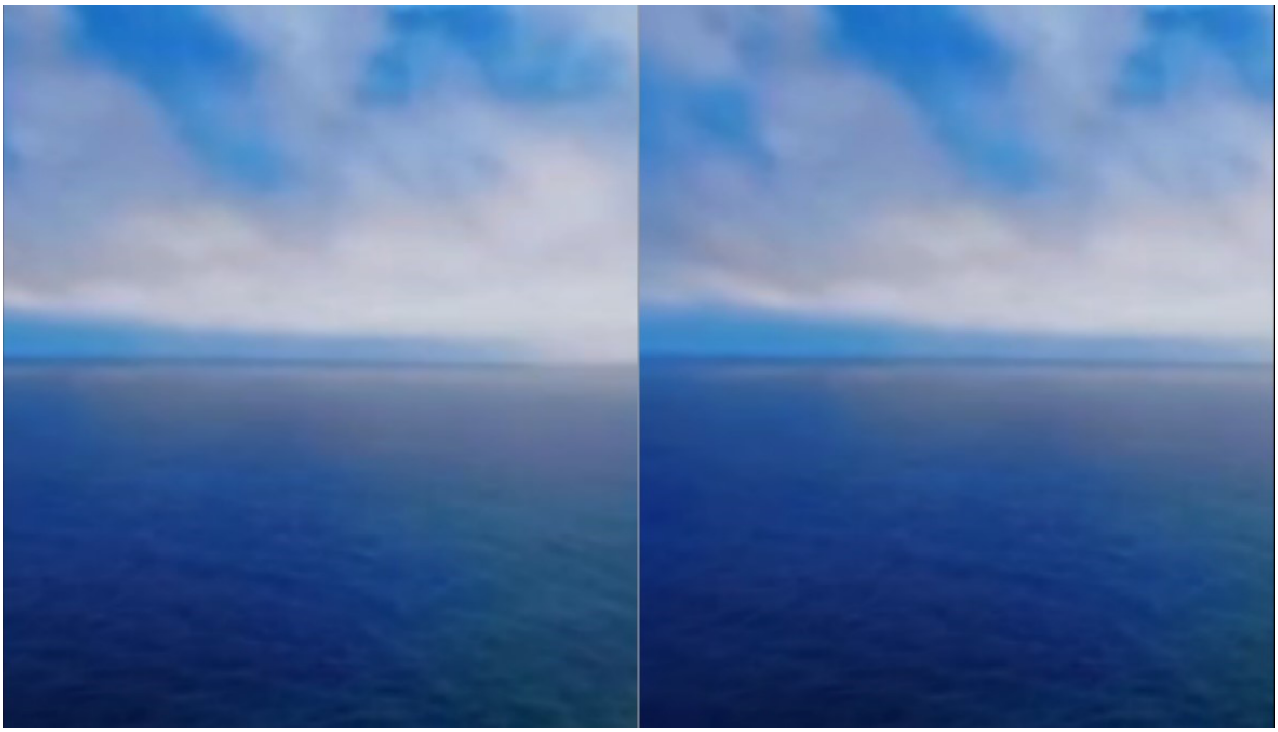

Fig. 2. The VR's environment of natural scenery. A sample picture of the 360 degrees video; when the patient turns her head to the right, left, up and down, the appropriate scene would place in front of her eyes as if she literally is in the environment.

3. Intervention

According to the literature review, findings show that light, nature, and video or VR can be effective in pain management. Therefore, the intervention of this study involved the synergistic applications of VR and nature factors. Also, the pre-test results were used to determine contents of in-

Table 1. Personal characteristics and pain, anxiety and nausea level of participants.

Group variable		VR Number (percent)	Non-VR Number (percent)	*P*-value
Educational level	< High school	2 (8.3)	2 (8.3)	0.66
	High school diploma	11 (45.8)	9 (37.5)	
	University	10 (41.7)	13 (54.2)	
Income level	Low	5 (20.8)	4 (16.7)	0.92
	Middle	12 (50)	13 (54.2)	
	High	7 (29.2)	7 (29.2)	
Job	House worker	19 (79.2)	17 (70.8)	0.50
	Job worker	5 (20.8)	7 (29.2)	
Abortion	Yes	5 (20.8)	6 (25)	0.73
	No	19 (79.2)	18 (75)	
Age	Mean (SD)	28.41 (4.50)	30.37 (6.09)	0.22
Weeks of gestation	Mean (SD)	40.04 (3.59)	38.29 (5.14)	0.17
Cognitive pain	Mean (SD)	4.04 (1.04)	4.29 (1.16)	0.43
Affective pain	Mean (SD)	5.20 (0.83)	5.37 (0.92)	0.51
Sensory pain	Mean (SD)	4.95 (1.08)	5.29 (1.04)	0.28
Anxiety	Mean (SD)	6.66 (1.52)	6.29 (1.16)	0.34
Nausea	Mean (SD)	5.12 (0.99)	5.50 (1.06)	0.21

tervention needs and duration of the intervention. In this pre-test, the content was evaluated before being presented to the experimental group by 5 obstetricians and 5 women similar to main participations of the study. As a result, one 360 degrees video of nature containing beach and peaceful landscape shown in Fig. 1,2 along with the sound of nature was considered appropriate. To present this video, an Android application was developed using the Google VR SDK (https://developers.google.com/vr).

It is worth to mention that the videos resolution were lowered and blurred to decrease motion sickness of VR, based on the research [24]. The head mounted display powered by a Samsung S3, and a noise reduction headphone was used. The patient's head movement was tracked using the Samsung S3's inertial measurement unit (IMU) sensor, and the appropriate content would place in front of the patient's eyes to reflect the head movement.

In order to start the study, the pain scores of contractions needed to be reported $\geq 4/10$. So, before beginning the study, the questionnaire including questions of pain components, anxiety, and nausea was given to the patient to assess their pain level. In this clinical trial, two interventions, each lasted almost 10 min (3 contractions at the first stage of labor and 2 contractions at the second stage of labor), were set. For each intervention, the participants in the VR group received help to wear the head mounted display and headphone, and then the same VR video was presented to them. Immediately after VR intervention the mentioned questionnaire was given to the patient to complete. The control group received usual care in each 10 min.

4. Statistical analysis

For categorical variables the number (percent) and for continuous variables the mean (standard deviation) was presented. To analyze the effect of VR immersion on each outcome (pain, anxiety, and nausea), we applied Chi-square test and independent *t*-test. Also, data were analyzed using IBM SPSS software version 20. The level of statistical significance was set at $P < 0.05$.

5. Results

Fifty-two women were included in our study, but four of them were excluded because they had a desire to use a pharmacologic intervention for pain control. Therefore, statistical analysis was performed on 48 women. Their mean age was 29.39 $\pm$ 5.39 years. The result of Chi-square test indicated that there was no significant statistical difference between the two groups in terms of distribution of educational level ($P = 0.66$), income level ($P = 0.92$), job ($P = 0.50$), and abortion status ($P = 0.73$). Also, based on the independent *t*-test, the mean of age ($P = 0.22$) and week's gestation ($P = 0.17$) were not significantly different in the both groups (Table 1).

We examined the mean of pain, anxiety and nausea levels in the intervention and the control groups based on the purpose of the study. Regarding the normal distribution of data, we used independent *t*-test. As the results show, the difference of means of pain, anxiety and nausea levels before the intervention were not statistically significant between the experimental and the control group (Table 1). Among the subscales of pain, the lowest was "cognitive pain" in women; whereas, the highest subscale was "affective pain" in the first stage in the both groups (Table 2). The mean score of cognitive pain was significantly lower among the intervention group (5.01 $\pm$ 1.41) in comparison to the control group (6.20 $\pm$ 1.17) in the first stage ($P = 0.013$). While, in the second stage, there was an insignificant difference between the two groups in terms of cognitive pain ($P = 0.55$) (Table 2). The mean score of affective pain was not statistically significant

Table 2. The comparison of the mean score of pain, anxiety and nausea before and after the intervention in two groups.

group variable		VR Mean ± SD	Non-VR Mean ± SD	*P*-value	Power
Cognitive pain	First stage (4-6 cm servix dilatation)	5.01 ± 1.41	6.20 ± 1.17	0.013	0.87
	Second stage (10 cm servix dilatation)	9.08 ± 0.77	9.20 ± 0.65	0.55	0.14
Affective pain	First stage (4-6 cm servix dilatation)	6.01 ± 1.35	6.54 ± 1.30	0.17	0.31
	Second stage (10 cm servix dilatation)	9.04 ± 0.95	9.30 ± 0.62	0.28	0.29
Sensory pain	First stage (4-6 cm servix dilatation)	5.20 ± 1.64	6.16 ± 1.37	0.033	0.57
	Second stage (10 cm servix dilatation)	9.01 ± 0.78	9.37 ± 0.57	0.064	0.43
Anxiety	First stage (4-6 cm servix dilatation)	6.58 ± 1.55	7.41 ± 1.21	0.045	0.52
	Second stage (10 cm servix dilatation)	6.37 ± 1.43	7.54 ± 1.58	0.011	0.74
Nausea	First stage (4-6 cm servix dilatation)	5.87 ± 1.19	6.58 ± 1.63	0.094	0.40
	Second stage (10 cm servix dilatation)	6.33 ± 1.52	6.62 ± 1.73	0.54	0.10

Table 3. The comparison of the median Apgar scores in two groups.

group	VR	Non-VR
Apgar (1 min)	8 (6-8)	7 (6-8)
Apgar (5 min)	9 (8-10)	9 (8-10)

between the two groups during the first and the second stage. Also, within the first stage, the mean score of sensory pain in the control group (5.20 ± 1.64) and the intervention group (6.16 ± 1.37) was significant ($P = 0.033$), while it was not significant in the second stage ($P = 0.064$) (Table 2). Regarding anxiety, there was a significant difference between the two groups in the two stages. The mean of anxiety was significantly higher in the control group in comparison to the intervention group. There was not a significant difference between the two groups in terms of nausea during the first stage ($P = 0.094$) and the second stage ($P = 0.54$).

It is worth to mention that Apgar scores at 1 and 5 minutes after birth performed on the babies by the midwife (it was not involved in the study). In the control and VR intervention groups, the 1-minute Apgar scores were 7 and 8, and 5-minute scores were 9 and 9, respectively (Table 3). No adverse events identified in the neonatal ward in either group.

6. Discussion

Overall, the results of this study show the efficacy of immersive VR in reducing sensory pain (worst pain possible), the amount of time laboring women spent thinking about their pain (cognitive pain dimension), and anxiety without increasing nausea during labor process. To the best of our knowledge, this study is novel for utilizing virtual reality distraction for pain relief during the first and the second stage of labor. Pain relief, anxiety and nausea at both stages of labor were assessed separately. The VR equipment employed in this randomized controlled research was fitting for use in a maternity ward (smartphone VR series and non-PC based). To point out the results in details, the primary outcome showed cognitive pain dimension (time spent thinking negatively about pain) and sensory pain dimension (worst possible pain) had a substantial reduction in the first stage of labor in the VR condition compared to the control group. Also, VR experience was strongly effective to mitigate anxiety during the both stages in the experimental group. As to the secondary outcome, among the intervention group, there were decreases in affective subscale of pain (feeling of unpleasantness) during the both stages and in sensory and cognitive components of pain in the second stage of labor, however, these reductions were not statistically significant.

The results are in agreement with other previous studies. Frey *et al.* [4] investigated the VR analgesia on 27 laboring women during the first stage of labor. Their outcome indicated the significant reduction of sensory pain (worst pain intensity) scores and lower affective and cognitive pain ratings in the VR condition than in the standard condition. Hoffman *et al.* reported that 22 participants (14 female and 8 male) experienced less pain when they were exposed to virtual environment (a 59% drop for women and a 41% drop for men) [25].

The feeling of presence in a virtual environment plays a central role in VR technology. Hoffman *et al.* in two studies used VR to reduce pain and anxiety of burn patients. They enhanced the distractive properties of a virtual environment by higher immersion and presence with the intent of increasing analgesic effectiveness [11, 14]. Similarly, in a study by Wiederhold *et al.*, virtual reality used as an adjunctive therapy for acute pain. They found that patients' engagement in virtual environment root in high presence and realism and concluded that this technology is significant not only for pain decrease but also for eliminating the interruptive nature of pain [26]. Moreover, they explored the immersiveness effect on physiology in a comprehensive review and found that there is a direct correlation between relaxing effects on physiological factors such as heart rate, respiration rate, skin temperature and immersion. In the present study, also, due to the presence in the virtual program, patients reported lower pain ratings.

JahaniShoorab *et al.* performed a study on primiparity women during episiotomy repair to determine the impact of video glasses on pain reduction. According to their results, pain intensity was significantly lower in the VR group than

in the non-VR group [27]. The results of the study by Pratiwi *et al.* indicated that primiparity women during the latent and active phases of labor experienced less pain intensity when they received VR intervention rather than only standard care [28].

Similar to other studies, there were several limitations in this study. Due to the restrictions of laboring women positions and conditions in the delivery room, we considered a passive VR condition. However, it was proved by Hoffman *et al.* [12] that interaction with virtual environment brings about more pain reduction. So, further studies utilizing more mobile and advanced VR system could potentially avoid this limitation. Moreover, some factors related to individual variability influencing pain scores were not considered in this randomized controlled trial because the between-group design attributed to not show subject differences such as variability in contractions, prior pain experiences, the ability to cope with pain, and so forth. A within-group study, therefore, could address this issue. These studies could evaluate the possible positive impacts of patient choice of nature scenes (e.g., beach versus mountain) on pain alleviation. Finally, the standard of VR distraction in labor process in terms of duration and frequency does not exist yet. The duration of VR condition in the present study was almost 10 minutes such as prior studies utilizing VR analgesia for acute pain [11], however, childbirth stages last many hours [3].

In conclusion, the findings of this controlled study reveal that virtual reality can function as an effective and feasible non-pharmacological technique to reduce pain and anxiety during childbirth process without causing nausea. However, further studies are needed to provide more evidence and verify these findings. Future research should focus on usefulness and ease of use of the software and mobility and comfortability of the VR equipment to better investigate longer duration of the VR intervention. Also, future research needs to study the impact of visual elements of design as well as characteristics of laboring women on pain control. Prehospital education and tailor made of VR content to draw patient attention are recommended.

Author contributions

Ali A. Safaei introduced the idea and designed the research study. Narges Momenyan performed the research. Sedighe Hantoushzadeh provided help and advice on the clinical trial and experiments. Ali A. Safaei contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

"All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of IR.MODARES.REC.1397.170 (approval number)". Clinical trial registration number :IRCT20181224042099N1.

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Conflict of interest

The authors declare no competing interests.

Data availability

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

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