Virtual Reality in Labor and Delivery for Reduction in Pain

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Title: Virtual Reality for pain reduction in Labor and Delivery

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Purpose and Hypothesis

The purpose of this study is to identify whether use of virtual reality devices can improve the pain management of women in labor and delivery. We hypothesize that use of virtual reality devices will result in a reduction in pain medication use, in epidural use, and prolong the duration of time prior to the patient receiving an epidural.

Background

The use of both medical and non-medical pain management in labor and delivery is ubiquitous in the United States. Among patients who undergo a vaginal delivery, 61 percent will require the use of epidural or spinal analgesia during their intrapartum course, with the highest rate of use being among Caucasian patients and those with higher levels of education (Osterman, 2011). However, many women choose complementary and alternative approaches to pain management in labor. These have included approaches as varied as hypnosis (termed hypnobirthing), biofeedback, acupuncture, and aromatherapy, with varying degrees of effectiveness (Tournaire, 2007).

As virtual reality technology has become more accessible in recent years, its utility in healthcare has been studied in several venues, mostly in its ability to reduce pain through a principle known as distraction analgesia. Virtual reality has been shown to be effective in reducing pain among patients requiring burn care (Das, 2005), during physical therapy (Hoffman, 2000), and even in the context of added noxious stimuli. Beyond even the subjective assessments of pain, the use of virtual reality has been shown to have an effect on the functional MRI findings in these patients, showing reductions in the degree of activity increases in areas usually associated with noxious stimuli.

A feasibility study of Virtual Reality has already been performed at our institution, and their findings indicated that younger patients were more open to attempting the use of the virtual reality system. Most users reported a positive experience with the system. There were no significant adverse outcomes, apart from some describing the goggles as uncomfortable (Mosadeghi, 2016). In addition, a prospective comparative cohort study was likewise performed at our institution which demonstrated a reduction in pain in the virtual reality-exposed cohort as compared to those subjects who were exposed to a calming nature video on a high-definition laptop (Tashjian, 2017).

We aim to perform a similar study to the latter above, but focused on reliving contraction pain in labor and delivery. We hypothesize that the use of virtual reality will reduce the patient's pain to a greater degree than no intervention. We will also qualitatively examine the subjects' satisfaction with and experience of virtual reality in labor and delivery as well as whether it had any effect on their need for pain medications or choice to receive an epidural.

Study Procedures

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This protocol is a randomized controlled trial of patients in labor at Cedars-Sinai Hospital.

Study Population and Period

The study population will consist of 40 patients: 20 in the VR arm and 20 in the Control arm (see below for sample size calculations).

We anticipate the recruitment and intervention portion of the study to be completed within 12 months.

The Inclusion criteria are as follows:

1. Female
2. >18 years old
3. English-speaking
4. Able to understand the goals of the study and provide informed consent
5. Pregnant with term gestation
6. Nullipara
7. Pain due to contractions rated from 4-7
8. Contractions at least every 5 minutes x 30 minutes preceding

The Exclusion criteria are as follows:

1. Parous
2. Use of medications for pain relief prior to the intervention
3. Use of an epidural
4. Preterm gestation
5. Pain not due to contractions
6. Pain score of 3 or below or 8 or above
7. Preeclampsia with severe features, eclampsia
8. History of epilepsy, dementia, or other neurologic disease that would prevent using VR
9. Sensitivity to flashing light / motion
10. Medical condition predisposing to nausea or dizziness
11. Injury to the eyes, face, neck, or arms that prevents comfortable use of VR hardware or software, or safe use of the hardware (e.g., open sores, wounds, or skin rash on face)

Patient Recruitment

Patients will be recruited by three methods. First, their obstetricians will be made aware of the study, given a study flyer, and asked to inform their patients of the ability to try alternative digital pain management options during their labor course. Second, patients will be informed of the availability of the study during their prenatal classes which are offered by the obstetric nurses at Cedars-Sinai. They will be encouraged to contact study staff (M.W.) on admission if they are interested in participating. Last, flyers will be present in labor and delivery making patients aware of the study and asking them to inform their nurse who will then inform study personnel (M.W.) if they are interested in participating.

Pre-Intervention Procedures

The study staff member will arrive at bedside, explain the risks and benefits of the study, and will obtain informed consent. Next, a physician or authorized study staff member will collect blood pressure and pulse data using standard sphygmomanometers in hospital wards, and will ask the patient to report current pain level on a 0 to 10 scale. We will also assess coping (Roberts, 2010) by asking “How are you coping with your labor?” We will also obtain all pain ratings collected and documented in the EHR during the current hospitalization up to 96 hours

before the intervention. Additionally, the study staff member will administer the **Quantitative Patient Survey** -- included at the end of this document and based on the NIH PROMIS Global Health Survey (10 items) and Childbirth Self-Efficacy inventory (15 items).

When a patient expresses interest in the study, she will then undergo randomization to either the VR arm or the Control arm of the study. Group assignments will be maintained inside sequentially numbered, sealed, opaque envelopes. After informed consent, study personnel will then open the assigned envelope and the study treatment will be revealed. Patients, providers, and study personnel will not be blinded to the assigned intervention.

For those patients randomized to VR, the study staff member will explain the use of the Samsung VR goggle set, and thereafter will allow the patient to use the device freely for up to 30 minutes. Intervals of 2-5 minutes is suggested for first-time use, and patients will be to allowed to discontinue it at any time as long as they are not experiencing any discomfort or side effects (dizziness, motion sickness, etc.). The study staff member will be present at all times, and will work with hospital staff as necessary to ensure the patient is receiving appropriate clinical care throughout the duration of the intervention.

For those patients randomized to the Control, the study staff member will explain that their assignment has been to the standard of care for which is no specific dedicated intervention at this time. Rather their intervention will only be further assessment of their pain scores, vitals, and medication use.

Post-Intervention Procedures

At the completion of either the VR or the Control intervention, the patients will be asked to Quantitative Patient Survey again, this time asking whether the preceding intervention would affect their responses to the questions.

A physician or authorized study staff member will collect blood pressure and pulse rate using standard sphygmomanometers in hospital wards, self-reported pain vitals, and assess coping. Then, the study staff member will ask the patient a series of questions about their experience (See Post-Intervention surveys in Additional Information).

Patients will spend 40 minutes to 1 hour with a member of the study staff during the inpatient stay, including both the initial intervention and interview time. Responses to the qualitative interview will not be audio- or video-recorded; instead, responses will be transcribed and later coded using qualitative data analysis software by study staff. Vitals collected immediately before and after the intervention will be recorded electronically; pain ratings up to 96 hours before and after intervention will be retrieved from the EHR by authorized study staff for analysis. All survey responses will be entered into a secure Redcap on a protected CSHS server.

Between participants, the VR device will be cleaned as detailed below.

Subject Participation End

The subject's participation will be completed when they wish to discontinue either intervention or at 30 minutes.

VR Intervention Details

As previously described, VR interventions have been used as distractions or diversions during medical procedures. This study will be one of the first to test the feasibility of deploying low-cost VR interventions in an obstetric hospital setting. The VR hardware configuration and all software

is currently being developed by AppliedVR, a leader in the development of medical applications for virtual reality technology, including interventions for weight loss and health, safety training, education, and personal development.

VR Hardware

This study will utilize a Samsung Gear VR goggle set, fitted with a Samsung Galaxy phone that delivers VR images and sound. We have added a sanitary cover to allow patients to use the same goggle set and phone without risk of contamination. Users will wear the VR goggles. Upon beginning their induction, the participants will also be given a brief "quick start" guide that orients them to turning on the unit and choosing modules. A member of the study staff team will then will re-introduce the patients to the hardware on the day of induction.

VR Hardware Placement and Cleaning

The Samsung gear device will be put in place as follows:

1. Patient places sanitary hair cap on head
2. Goggle is fitted with disposable sanitary cover and foam backing that affixes with Velcro to inside of face mask
3. Patient places goggle headset on him/herself and adjusts straps.

Between patients, the device will be cleaned as follows:

1. Headset will be removed; and disposable head cap, sanitary cover and foam backing will be thrown in sanitary waste bin in inpatient room.
2. Fabric strap will be cleaned by coordinator using Virex, approved cleaner for medical fabrics and let sit for a minimum of 10 minutes before next use.
3. Plastic housing of device will be cleaned using Sani-wipes and let sit for a minimum of 2 minutes before next use.
4. Inside and outside of the lenses of device will be cleaned using approved lens cleaner containing alcohol.

VR Software

Next, we will continue to work with AppliedVR to develop appropriate VR environments for use by laboring patients. We will refine these environments given feedback from CSMC staff. These environments are not being developed specifically for any particular patient, and any participant may select any module. These modules will use 3D visual and audio cues to immerse the patient. Software modules may be used for as long as a patient wishes, but for this study, we are recommending 2-5 minutes for first use, and a maximum of 20 minutes for total use time per session.

Proposed VR interventions include the following:

1. Paint Studio: The patient will move his or her head around to paint an abstract image on canvas. Paint strokes are controlled by movement speed. Patients can also tour their own art studio.
2. TheBluVR: Patients select from several ocean environments (e.g., Arctic) by touching a trackpad on the side of the Gear VR goggles. Sea creatures swim up to the patient.
3. Concert Performance: Watch Cirque du Soleil perform from the stage. The patient can look around the environment in 360 degrees as the performance happens.
4. World Flyover: Patients fly over photorealistic views of world landmarks, allowing them to visit famous places from the hospital bed.

5. Pain RelieVR: Patients shoot at targets in an energetic cartoon world, while soothing music plays.

Outcomes and Data Collection

Primary Outcome: Reduction in pain scores from pre- to post-intervention

Secondary Outcome:

1. Duration of use of the intervention
2. Acceptability of the intervention
3. Need for IV pain medication during the intervention
    a. Time to IV pain medication after the intervention
4. Request for an epidural during the intervention
    a. Time to epidural use after the intervention
5. Vital sign changes during and after the intervention including heart rate and blood pressure.

Data Collection

1. Baseline maternal demographics
    a. Name and Medical Record Number (secured and stored separate from all other data below)
    b. Age
    c. Race/Ethnicity
    d. Insurance status
    e. Gravidity/Parity
2. Admitting diagnosis
3. Obstetric data
    a. Gestational age
    b. Induction agents
    c. Mode of delivery
4. Vital Signs (blood pressure, heart rate) before, during (continuous pulse oximeter and blood pressure measurements every 10 minutes) and after the intervention.
5. Pain scores before and after the intervention. Average Pain Rating during 4 hours before intervention, and Average Pain Rating after intervention (up to 24 hours).
6. Pain interventions including time to first use of IV pain medication and first use of epidural.
7. Responses to **Quantitative Patient Survey** (PROMIS Global Health pre-intervention, and modified Childbirth Self-Efficacy Inventory pre- and post-intervention)

8. Responses to **Qualitative Interview**

Sample Size Calculations

We will compile data from qualitative interviews, and summarize key points about the intervention brought up by patients. This report will further guide development and refinement of the inpatient VR intervention.

We will also examine changes in scores on patient-reported pain, blood pressure and pulse rate. We will compute change scores for each of these measures and also compare these patients to the Control group. If data are normally distributed, we will use a paired Student's t test for comparisons pre- and post-intervention, and two-sample t tests for between group comparisons. If data are abnormally skewed, we will conduct similar analyses using the non-parametric Wilcoxon signed-rank test, and the Wilcoxon rank-sum test, respectively.

We are uncertain of the degree of change we will observe in patient responses to the Quantitative Patient Survey (PROMIS + CSEI), pain ratings, and cardiac vitals after exposure to the VR intervention, as a study of this type has not been previously conducted.

We have decided instead to use established, clinically-meaningful changes in pain ratings as a means of estimating change. Previous studies have shown that for the minimum clinically important difference in pain scores varies by baseline starting pain level. For those subjects starting with a baseline pain level of 40-70 mm (as in our planned cohort), the minimum clinically important difference is 13 mm (Olsen, BMC Medicine 2017).

For all analyses, we will assume a 5% Type I error rate (alpha) and a 20% type II error rate (or 80% power). If we assume that the baseline median pain level of our patients is 55 mm, then for within group analyses to show a 13 mm reduction in pain would require 20 patients in each arm for 40 patients total.

Therefore, to conduct one RCT of the effect of VR on pain starting at a median level of 55 mm, we would need 40 patients:

[Control (20 patients)]

[VR (20 patients)]

We will also perform between group analyses, we will compare pain scores obtained from all inpatients exposed to the VR intervention to the Control. Our calculated sample size will also be adequate to identify a difference between groups.

Potential risks and benefits to the subjects
Benefits:

To Individual: Patients will likely enjoy using the VR interventions, which are immersive and impressive upon cursory use. We anticipate that patients may report greater satisfaction, pain management, and overall health during the study.

To Society: This is the first study on the use of virtual reality in an Obstetric setting. Knowledge gained could be used to improve patient satisfaction and pain management with care across all hospitals.

Risks:

Patients using the virtual reality intervention may experience side effects common to users of VR and individuals who view 3D video, including motion sickness, dizziness, eye strain, headaches, or other visual abnormalities. If patients experience these symptoms, they will be asked to stop using the VR software for 15 minutes, and will be allowed to continue if they agree and wish to proceed. A small number of patients (up to 0.025%) may experience seizures or severe symptoms (e.g., disorientation, nausea, or drowsiness) upon viewing the virtual reality experience. Seizures from flashing light are more common in children and epileptic patients (who are excluded). To minimize this concern further, we have not incorporated flashing lights into the VR experiences. We have also excluded patients who might be at a priori higher risk for seizures including those with hypertensive disorders of pregnancy.

Some patients may find the VR goggles uncomfortable to wear or confining. To date, patients with claustrophobia have not reported discomfort using VR goggles, as they are often used in treatment of that condition. Nevertheless, individuals previously diagnosed with claustrophobia should discontinue use if they feel uncomfortable. A trained study staff member will be on hand at all times to ensure patient safety.

Patients will also be asked questions that some might consider sensitive in nature, such as perceptions of one's own general mental health, distress, and anxiety. These items may make patients feel uncomfortable or embarrassed. Patients are reminded that they can skip any or all questions that make them feel uncomfortable. Also, patient answers will not be entered into the electronic medical record. Patients may be contacted by CSMC mental health professionals if they give concerning answers, but they can refuse care. These interactions will not impact future care received at CSMC.

Data Security and Privacy:

Data will be abstracted from the EHR by approved staff, and will be transmitted securely to study staff. Staff data collection will be limited to variables mentioned previously. Demographic and clinical data, as well as Qualitative Interview responses will be entered into a secure database and stored on secure servers at CSMC. We will not collect Social Security numbers, and we will use sequential Unique ID numbers to track patients in the study.

How the research differs from Standard of Care:

There is no fixed standard of care for management of pain in labor and delivery and the experience varies by patient and nursing/physician providers. No alterations will be made to the pain management options available for the patient. Rather -- for those patients randomized to the VR arm -- an additional method of pain management will be made available but with no restriction on the use of other pain management methods as desired by the patient.

Justification for record review for recruitment

We will initially contact the patient's obstetrician to assess whether they feel their patient would be an appropriate candidate for the study. If the patient's obstetrician permits, we will then ask the patient about the study through a resident or nurse member of the staff providing clinical care for the patient. If at that time the patient expresses interest, a member of our study staff will contact and obtain consent from the patient.

Age, gender, gravidity/parity, and gestational age are necessary to assess that a patient meets the appropriate inclusion criteria. Self-identification via flyer is considered (and is another

option); however, the patient may be in pain at the time of arrival to labor and delivery and so might not self-identify that she is a candidate. In order to establish a standardized patient population, similarly pain scores and tocometer reading (contractions assessment) is needed. Because of the rapidly changing nature of these assessments, identification ahead of time and self-recruitment would not be possible.

Pre-Intervention Patient Quantitative Survey

PROMIS-10 Global Health Survey

Before we begin please respond to each item by marking one box per row.

	Excellent	Very Good	Good	Fair	Poor
In general, would you say your health is:					
In general, would you say your quality of life is:					
In general, how would you rate your physical health?					
In general, how would you rate your mental health, including your mood and your ability to think?					
In general, how would you rate your satisfaction with your social activities and relationships?					
In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)					

	Completely				Not at All
To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?					

	Never				Always
How often have you been bothered by emotional problems e.g. feeling anxious, depressed, or irritable?					

	None				Very severe
How would you rate your fatigue on average?					
How would you rate your pain on average?					

VR Interest / Exposure Survey

	Not interested				Very interested
Have you used virtual reality devices before? (Yes/No)	-	-	-	-	-
What is your perception of the use of virtual reality devices in labor and delivery for improving coping?					

Birth Preferences for Pain

What are your plans for coping with labor pain? (circle all that apply)

> Acupuncture, acupressure, aromatherapy, biofeedback, hypnosis, massage therapy, hydrotherapy (tub), oral pain medications, IV pain medications, epidural, other

Did you attend childbirth education classes? (Yes/No)

Have you taken classes/training in any of the following methods of coping with labor pain?

> Acupuncture, acupressure, aromatherapy, biofeedback, hypnosis, massage therapy, hydrotherapy (tub)

Pre-Intervention Patient Quantitative Survey (cont.)

Childbirth Self-Efficacy Inventory

For each of the following behaviors, rate the extent to which you feel you will be able to perform this during your labor.

	Not be able to perform				**Easily perform**
Relax my body.					
Get ready for each contraction.					
Use breathing during labor contractions.					
Keep myself in control.					
Think about relaxing.					
Concentrate on an object in the room to distract myself.					
Keep myself calm.					
Concentrate on thinking about the baby.					
Stay on top of each contraction.					
Think positively.					
Not think about the pain.					
Tell myself that I can do it.					
Think about others in my family.					
Concentrate on getting through one contraction at a time.					
Listen to encouragement from the person helping me.					

Post-Intervention Patient Quantitative Survey

Childbirth Self-Efficacy Inventory

For each of the following behaviors, rate the extent to which you feel having access to the a Virtual Reality intervention would be helpful to you in coping with active labor.

	Not at all helpful				**Very helpful**
Relax my body.					
Get ready for each contraction.					
Use breathing during labor contractions.					
Keep myself in control.					
Think about relaxing.					
Concentrate on an object in the room to distract myself.					
Keep myself calm.					
Concentrate on thinking about the baby.					
Stay on top of each contraction.					
Think positively.					
Not think about the pain.					
Tell myself that I can do it.					
Think about others in my family.					
Concentrate on getting through one contraction at a time.					
Listen to encouragement from the person helping me.					

Post-Intervention Qualitative Survey

Patient Interview Script

We want to thank you for your participation in the study and for agreeing to talk with us today. This interview will take approximately 10-15 minutes, and we will ask you a number of open-ended questions about your thoughts and feelings about wearing the Virtual Reality device and "participating" in the experiences. There are no 'right' or 'wrong' answers to any of these questions: we want to hear about your experience and listen to your opinion, in your own words.

General "Think Aloud" Probe

When you think about your experience participating in the Virtual Reality study, what is the first thing that comes to your mind?

Participating in the Intervention:

Would you like to participate in a study like this one again? Why?

How did participating in this study make you feel?

(PROBES: distracted, happy, confused, dizzy, anxious, at ease, etc.)

The VR Device:

If a friend or family member asked you about the device, what would you tell them about it?

How comfortable were you wearing the device?

Did you have any concerns about the device while you were using it? If so, what were they?

Did you have any questions about the device while you were using it? If so, what were they?

(Researcher should record if patient asked questions about device while using it)

Do you have any thoughts on how the device can be improved?

VR Experiences:

What was your favorite part about watching the 'experiences'?

What was your least favorite part about watching the 'experiences'?

Did you try multiple 'experiences'? If so, which was your favorite?

What would be your ideal 'experience' duration? (e.g. how many minutes long would you want them to be)

Did you have any concerns while you were watching the 'experiences'? If so, what were they?

Did you have any questions while you were watching the 'experiences'? If so, what were they?

If at all, how do you think the 'experiences' can be improved?

What would you like to see in additional 'experiences'?

Perceived Effects of Participation:

Do you think that wearing the device affected your anxiety level? [IF YES:] How so?

Do you think that wearing the device affected your pain? [IF YES:] How so?

Future Directions

Would you recommend the use of VR for reducing pain in women in labor?

Would you recommend the use of VR in other settings during your pregnancy or postpartum period?

These are all the questions we have for you today. Is there anything we didn't mention that you would like to discuss?

Thank you again for your participation in this study, and please feel free to contact our research team members if you have anything else you would like to discuss with us about this project.