TITLE:

Feasibility of an Immersive Virtual Reality Intervention for First Trimester Abortion: A Pilot Study

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ABSTRACT:

Perception of pain during surgical abortion is nuanced and affected by physical as well as psychosocial factors—notably the experience of anxiety—which can significantly increase perceived pain during abortion. It is found that women who suffer from anxiety are more likely to experience greater pain during gynecological procedures. Furthermore, pain management in the setting of gynecologic procedures is complex. While local anesthesia is commonly used, studies suggest that multimodal approaches may be more effective methods of pain management during gynecological procedures. However, the application of non-pharmacological pain and anxiety control adjuncts during gynecological procedures is not well studied, especially with regards to first-trimester surgical abortion. Recent innovation in virtual reality (VR) has generated increased interest in its potential use as an innovative and non-invasive method for managing patient anxiety and subsequently decreasing acute pain. Our work will assess the practicality and qualitative experiences of women using VR during first-trimester surgical abortion at the University of California Los Angeles West-Medical Obstetrics and Gynecology Clinic. Through this mixed method pilot study, we will evaluate the feasibility of using VR and its effect on procedure-related anxiety in the setting of first-trimester surgical abortion. Our work ultimately seeks to improve the experience of women undergoing first-trimester surgical abortion.

BACKGROUND:

a) Rationale:

Perception of pain and anxiety in first trimester surgical abortion

Most women experience moderate to severe pain during first-trimester surgical abortion despite various analgesic techniques.[1, 2] It is well-known that physiologic factors such as young maternal age, nulliparity, and a history of dysmenorrhea are associated with higher pain scores during first-trimester abortion. In addition, psychosocial factors play a large role in perception of pain during the procedure. These non-physiologic factors may include pre-procedural anxiety, fear, a sense of stigmatization or isolation, and self-assessed low pain tolerance. Of all these psychosocial factors, pre-procedural anxiety has the highest correlation with increased perception of pain during the surgical procedure.[3, 4, 5] Accordingly, it has been found that pain management during gynecologic procedures is complex.[6] While local anesthesia is commonly used, studies suggest that multimodal approaches, such as visual or auditory distraction, oral medication, and emotional support may be more effective methods of pain management during gynecological procedures.[7]

Virtual Reality

Figure 1. Example of Virtual Reality Headset

Virtual reality (VR) is a three-dimensional experience created by a headset fitted with a video display. The device, designed to be worn on the face, immerses the viewer in a virtual world and can create a visual and auditory distraction from the patient's present situation (*Figure 1*). VR devices are easily portable, intuitive to use, and non-invasive. Recent innovation in VR has generated increased interest in its potential use as a non-pharmacological adjunct for managing patient anxiety and subsequently decreasing acute pain.

Previous Studies and Scientific Significance

Studies have shown that VR is effective in reducing anxiety among a range of patients in differing circumstances, from patients undergoing dental procedures to patients undergoing chemotherapy.[8, 9] A recent randomized controlled trial has found that pre-operative VR can significantly reduce anxiety and increase patient satisfaction among patients undergoing craniotomy and spinal surgery.[10] A study evaluating the feasibility of using VR among hospitalized patients revealed that most patients had positive experiences with VR and felt that it was not only capable of reducing anxiety but also pain.[11] Specifically, in the field of obstetrics and gynecology, a study showed that women undergoing episiotomy repair report markedly lower levels of anxiety after using VR as a form of adjunct pain therapy when compared to those who have not.[12] To our knowledge, the application of VR to first-trimester abortion has not been studied, and it is worthy of further research.

b) Objectives and Specific Aims:

1. *Assess the feasibility of using VR during first trimester surgical abortion under local anesthesia*:

Our work will assess the practicality and qualitative experience of women using VR during first trimester surgical abortion under local anesthesia. Semi-structured interviews will be conducted to understand the patient's experience of using VR.

2. *Understand the effect of VR on procedure-related anxiety during first trimester surgical abortion*: We will analyze the anxiety scores of women before and after surgical abortion with the use of VR. In order to obtain an effect size for future studies, we will enroll a control group of patients receiving standard care and compare the anxiety scores between the two groups. The mean and standard deviation of anxiety scores for each group will be used to calculate power for future studies.

RESEARCH METHODS AND DESIGN

i) Trial Design/Sample Size:

We will conduct a mixed method pilot study to assess the feasibility of VR and understand its potential to decrease anxiety in the setting of first-trimester surgical abortion.

Specific aim 1: We will enroll a convenient sample of 15 participants who will use VR during first trimester surgical termination under local anesthesia in our clinic. Anxiety scores will be recorded before and after the procedure using a visual-analog scale. After the conclusion of the procedure, we will conduct semi-structured interviews to understand their overall experience with the VR device and software. We will ask patients to describe their experience in their own words and without prompting. This will then be followed by scripted probes regarding specific experiences with the VR use during the procedure and its effect on anxiety and pain. The interviews will be audio-recorded for analysis. We believe that this sample size will allow us to obtain thematic saturation to analyze patients' experiences.

Specific aim 2: After enrollment of the experimental group, we will enroll 15 patients receiving standard care in our clinic to compare the anxiety scores before and after the procedure. The enrollment of thirty patients will serve as a convenient sample in order to obtain an effect size. This data will help power further studies to determine the significance of VR on anxiety management.

ii) Participants:

We will screen patients over 18 years of age presenting to our obstetrics and gynecology clinic for first-trimester surgical abortion. Eligible patients must be English-speaking women seeking elective first trimester surgical abortion under local anesthesia. Patients will be excluded from the study arm if they have a history of motion sickness or vertigo, seizures or epilepsy, recent eye surgery, visual impairment, or claustrophobia. We will also exclude patients diagnosed or treated for anxiety in the past.

iii) Study setting:

The study will take place at the UCLA West-Medical Obstetrics and Gynecology clinic, which in the past year (from 1/1/2016 to 12/31/2016), has helped women receive a total of 160 first-trimester surgical abortions under local anesthesia. Due to the high volume of potential patients, we expect ease of enrollment.

iv) Virtual Reality:

We will use a commercially available VR device, comprised of a phone, headset and headphones. The phone is inserted into the headset to act as the visual display that can create different three dimensional environments. The device will require a wireless internet connection to work effectively. The patient will choose the virtual reality experience she prefers. More information about VR can be found at: appliedvr.zendesk.com

v) Outcome measurements:

We will collect standard demographic information (age, pregnancy history, ethnicity, race, educational and income level) from all participants using standard cross sectional survey. For each patient who has used the VR experience during the procedure, a pilot period measurement tool (Appendix A) will be administered after the recovery period. We will conduct a qualitative semi-structured interview in a private room (Appendix B). Audio-recordings of the patient's experience will be collected.

Anxiety scores: To assess the effect of VR on managing anxiety, we will measure the patient's perceived anxiety through survey scoring. Preoperatively, two surveys will be administered—a modified Amsterdam Preoperative Anxiety and Information Scale (modified APAIS) (Appendix C) and a visual analog scale for anxiety (numerical score with 0=minimum score 10 =maximum score) (Appendix D). The visual analog scale will again be used after the procedure.

vi) Statistical analysis:

In our qualitative analysis, interviews will be recorded and transcribed verbatim, and analyzed for thematic content using the Dedoose online software platform. Two members of the research team will code each transcript independently, with discrepancies resolved by consensus. For the quantitative component, the VAS scores, descriptive analysis using means and proportions for each variable of interest will be performed. Patterns of missing data will be assessed and imputation methods will be considered if appropriate. We will use mean and standard deviations for each group to detect the effect size for future studies.

IMPACT STATEMENT

Despite various analgesic techniques, first trimester surgical abortion is associated with significant pain, and the perception of pain, especially during abortion, is nuanced and affected not only

by physical but also by psychosocial factors.[13] It has been shown that women present increased symptoms of anxiety, depressiveness, and stress before abortion, and that these symptoms can be significantly exacerbated by the perceived stigma of abortion.[14] Because VR has been successful in decreasing anxiety and increasing patient satisfaction in various patient cohorts, it is worth exploring its possible use in first-trimester surgical abortion. The application of VR to the field of gynecological procedures has been limited, and to our knowledge, VR has never been offered to women seeking first-trimester surgical abortion. Our project will be the first to evaluate the feasibility of VR use during first-trimester surgical abortion. If feasibility is established, this pilot data will help us perform adequately powered future studies.