A randomised controlled trial to assess the feasibility of utilising virtual reality to facilitate analgesia during external cephalic version.

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Abstract

External cephalic version (ECV) is associated with a moderate degree of pain. Virtual reality (VR) is a technology that has shown promise in offering procedural analgesia. We undertook a clinical pilot to assess the efficacy of VR to reduce pain during ECV. In an open randomised controlled trial (RCT), 50 women were assigned to either VR or standard care (25 per group). VR content (Sky Lights) was administered via a headset and pre-/post-procedural measures of pain, anxiety, device experience and vital signs were measured. There were no significant differences between groups (VR/no VR) in pain scores (60.68 vs 49.76; p=0.2), ECV success rates (80% vs 76%; p=0.7) or anxiety levels. The women receiving VR had a significantly higher anticipation of pain pre-ECV (70.0 vs 50.0; p=0.03). 20 (80%) of the VR women indicated that they would use VR again and 22 (88%) indicated they would recommend it to a friend having ECV. There were no significant differences between groups for side effects encountered or changes in vital signs. We have shown that VR use during ECV is feasible and appears safe.

Objectives

The objective of this pilot was to assess feasibility of concept and lay the foundations for an adequately powered RCT to test the performance of VR against the standard of care for all women undergoing ECV.

Primary outcomes involved assessing:

- Between group differences in scores for pain and anxiety;
- Between group differences for physiological parameters [heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP)];
- Acceptance/feedback of the procedure;
- Side effects encountered between the intervention (VR) and control (no VR).

Secondary outcomes involved exploring associations between patient factors and the levels of pain encountered during ECV.

Methods

Randomisation:

Patient allocation was performed using a randomisation sequence. This was generated in Microsoft Excel 2018 with a 1:1 allocation using random block sizes of 10. Based on this, patients had either the intervention (VR) or standard care (control/no analgesia) administered to them prior to the ECV.

Trial Design:

Prior to the ECV, women were provided with questionnaires to assess their pre-procedural disposition towards pain and anxiety using 101-point numerical rating scales. This was followed by recording the participant's demographic data and their HR and non-invasive blood pressure (NIBP). Patients were administered 250µg terbutaline for tocolysis and the ECV was then performed by an experienced operator.

Following the procedure the number of attempt(s) and duration of ECV were recorded. The clinician was also asked to classify the difficulty of the procedure drawing upon previous experiences.

Post-ECV physiological parameters were also recorded within 5 minutes of ECV completion. Women from both groups were then given a questionnaire to assess their pain, experience, and screen for side effects.

Description of the Intervention:

VR Device: Samsung Galaxy S8 + Samsung Gear VR with Bluetooth controller/touchpad.
VR Content: Sky Lights (Alo VR, Singapore).
In Sky Lights, the user is placed lying down in a quiet field, staring at a starry night sky with several unlit Chinese lanterns floating gently above. By focusing their gaze on a lantern, the user is able to set it alight, causing the lantern to rise up and away. As reward for continued participation; a lit lantern will either set off a series of fireworks or form Lantern Festival shapes such as a dragon or a giant fish. Relaxing background music is also played to provide auditory stimulation.

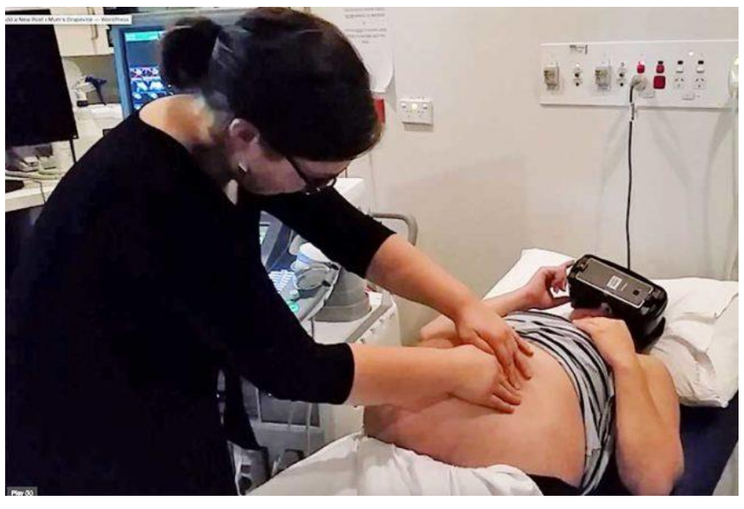
Results

Pre-ECV:

- Anticipated pain towards the procedure was significantly higher in the VR group than the control group [Median = 70 vs 50; p=0.03].
- No significant differences between groups in relation to their pre-procedural anxiety, physiological parameters or attitudes towards the procedure.

Post-ECV:

- No statistically significant differences between pain score [60.68 (±21.1) vs 49.76 (±28.00; p=0.17], ECV success rates (80% vs 76%; p=0.73), and physiological parameters pre- and post-intervention.
- Side effects presented in 25.5% of the participants but was not significantly different between VR and control groups (24% vs 28%; p=0.75).
- 20 women (80%) indicated that they would use the VR again in a subsequent ECV
- 19 (76%) believed it should be offered as a routine part of the ECV.
- 22 (88%) said that they would recommend it to a friend undergoing ECV.
- Secondary outcomes identified several significant variables and demonstrated moderate correlations with reported pain for: ECV duration (ρ = 0.37; p=0.01), pre-ECV anxiety level (ρ = 0.36, p=0.03), procedure difficulty (ρ = 0.36; p=0.01), and anticipated pain (ρ = 0.40; p=0.02).



Conclusion

This pilot serves as preliminary evidence for the feasibility, safety and acceptance of VR use during ECV. The study further informs future controlled studies on the issue to systematically investigate its utility during the procedure.

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