**The Use Of Virtual Reality Goggles As A Distraction Tool To Decrease Pain And Anxiety In Painful Image Guided Procedures In Pediatric Patients:**

**A Pilot Feasibility Study**

**Background and Rationale:**

Pediatric patients are a vulnerable patient demographic, subject to many painful diagnostic and therapeutic procedures that are necessary for treatment planning and successful treatment outcomes, especially oncology patients.1 Pain is a frequent problem related to cancer treatment and is associated with significant fear and distress for patients and families 2,3,4,5,6. Similarly, non-oncologic pediatric patients may also undergo painful procedures for a variety of diagnostic and therapeutic procedures.7 Unlike adult patients, in the pediatric population, even the simplest percutaneous procedures may require general anesthesia or sedation, which increases the risk of adverse outcomes, and the cost of care.8,9 Furthermore, there are many minor but necessary procedures in which sedation is either not indicated, not possible, or it’s delivery is less than optimal. In these cases, painful procedures are performed on children who are resistant, crying, and/or require restraint. This undesirable situation leads to distress affecting the child, family and medical personnel, in addition to adverse procedural outcomes and secondarily, less effective care.10 The use of local anesthesia for some of these procedures is painful to administer and usually comes at the cost of increased anxiety, prolonged procedure time due to patient inability to cooperate, and increased risk of complications due to patient movement and restlessness.10

The use of multimedia tablets (e.g. iPads), or portable DVD players has assisted in the distraction of pediatric patients pre-procedure.11 However, patients remain aware of their surroundings in terms of medical staff around them, or frightening equipment in procedure rooms, particularly during painful stimuli.11

Virtual reality (VR) goggles have recently been introduced to the healthcare field, in spite of being available on the market for almost 2 years to consumers. VR offers an immersive environment that occupies a user’s entire visual field as well as an audio experience that masks noises in the patient’s surroundings. VR goggles have the potential to function as a visual barrier, a distraction technique, and an immersive experience, which may decrease a patient’s perception of pain and anxiety levels.12

Hoffman et al. have demonstrated that immersive VR is effective for the treatment of acute pain in adults13. In this study, which involved 9 healthy subjects receiving thermal pain stimulation, VR was found to have similar efficacy to opioid therapy. However, unlike opioid therapy, the impact of VR on pain was not associated with a tolerance effect.14 VR has also been established to be effective in the management of pediatric burn patients during wound dressing change; a procedure that is known to be very painful.15,16,17

In the field of interventional radiology (IR), the implementation of VR as a method of pain distraction may result in: (i) decreased reliance on sedation and opioids for these children during minor procedures, and (ii) decreased utilization of anesthesia (and its related risks, complications, resources). Secondarily, VR also has the potential to: (i) improve the psychological and emotional well being of patients and families, (ii) decrease the cost of care (by increasing timely access to procedures, as well as decreasing procedure time and use of resources), as well as (iii) decreasing morbidity and mortality.

Literature continues support novel uses and applications for VR, and the results have been promising.18,15,19,20,21,22

**Research Project:**

Objective: To examine the feasibility of administering VR as a method of reducing pain and anxiety in a pediatric pilot group of patients undergoing image-guided IR procedures at Sick Kids.

Hypothesis: VR is an effective method for reducing pain and anxiety during image-guided IR procedures.

Study Design and Setting: We will apply a prospective pre-post design to evaluate the feasibility of VR in the Image Guided Therapy Suite at Sick Kids. In the context of this pilot feasibility study, we will examine: (i) patient recruitment and dropout rates, (ii) time to demonstrate VR, (iii) patient and family satisfaction with VR, and (iv) effect of VR on pain and anxiety levels and iv) total procedure time.

Methods:

Following ethics approval, we will recruit a pilot sample of 30 patients from the Image Guided Therapy Suite.

Inclusion criteria:

1)Patients aged 8 -18 years old undergoing interventional procedures that could be performed under local anesthesia or sedation, including peripherally inserted central catheter (PICC) insertions and exchanges, percutaneous biopsies, ascitic tapping (therapeutic and diagnostic), pleural tapping (therapeutic and diagnostic), g-tube / c-tube changes, central venous line management and tube and line removals, linograms.

2) Patients without delayed cognitive milestones.

3) Patients with physical characteristics allowing for VR goggles to be used (suitable head circumference and inter-pupillary distance of 45 mm), i.e. older than 8 years old.

4) Patients receiving oral sedation.

Exclusion criteria:

1) Patients aged 0 - 7 years old.

2) Patients undergoing procedures requiring general anesthesia, or not suitable for sedation or local anaesthesia.

3) Patients with delayed cognitive milestones.

4) Patients physically not suitable for VR (small or large head circumference (does not fit goggles strap) or short inter-pupillary distance (45mm), i.e. less than 8 years old.

5) Patients that are under the care of CCRT, candidates for general anesthesia or patients that are classified as ASA 4-5 (high risk patients).

6) Patients with history of anxiety or diagnosed as having an anxiety or psychiatric disorder / claustrophobia.

7) Patients receiving IV sedation

8) Patient / parental refusal.

Patients may be recruited during an IGT clinic visit or while waiting for their turn in the IGT observation room, where they will have privacy and personal space.

Following informed consent and before the painful procedure, the participant will complete validated measures of pain23,24 and anxiety25. Retrospective distress will be measured using the Colored Analogue Scale (CAS). The MYPAS (Modified Yale Preoperative Anxiety Scale) will be used to measure peri-procedure anxiety. Patient and parent satisfaction will use the SUS (System Usability Scale).

During the procedure, they will wear the VR goggles. They will experience a calm immersive environment with no sudden stimuli. If the patient experiences any pain or discomfort the VR experience can be immediately terminated by the patient or any of the team members by simply taking off the goggles. The time required to wear the goggles and the time needed to complete the procedure will be recorded. Immediately following the painful procedure, the participant will complete the pain and anxiety measures again. Data will be analyzed using SPSS software.

Strength of Team: We currently have a multidisciplinary and inter-professional team of interventional radiologists, interventional radiology nurses, anesthesiologist, pain scientist, and an oncologist involved on this project.

Next Steps: The results from this pilot feasibility study will be used to refine our methodology prior to a larger, definitive study to evaluate the effectiveness of VR as a sedation technique on par with other non-pharmacologic techniques in our department.

Impact and Relevance: Success of this project would have a significant impact on the pain management and well-being of pediatric patients with and without cancer undergoing painful IR procedures. In adult populations, the success of IR is partly due to its minimally invasive nature, with increased safety and decreased morbidity and mortality compared to alternative open surgical procedures. However, it is also largely dependent on the ability to perform many IR procedures under local anesthesia. The ability to shift at least a small portion of our pediatric sedation or general anesthesia demographic to VR with local anesthesia (± some oral sedation) would have a positive impact decreasing the IV sedation or anesthesia risks, decreasing pain and anxiety, decreasing cost of care, as well as timely access to procedures and improved patient through-put in IGT.

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