Title of the study: Virtual Reality Distraction for Procedural Pain Management and Anxiety in Children With Burn Injuries: A Pilot Study

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BACKGROUND

The burden of burns and pain. Burn injuries are among the leading causes of visits to the emergency department and hospitalizations in young children. They mostly result from scalds and contact with household appliances. Regardless the cause of the injury, dressing changes and hydrotherapy sessions for burn injuries are associated with extreme pain. The management of acute pain experienced during hydrotherapy sessions in patients with burn injuries, called procedural pain, remains a major challenge for healthcare professionals. Pain can have several short term effects on the child on the development, mood, sleep, appetite, school performance, anxiety and distress levels. In the long term, it can decrease the pain threshold, cause stress disorders, affect social behavior and seeking of medical services. In burn injuries, pain is often accompanied by great anxiety, which in turn, decreases pain tolerance. To relieve pain and anxiety, clinicians usually rely on pharmacological agents via the administration of high doses of opioids and anxiolytics. The use of these medications can cause deep sedation in children, and many side effects such as nausea, vomiting, and respiratory depression. Also, despite the growing use of opioids, patients report pain of more than 7 on a scale of 0-10 during their dressing changes and hydrotherapy sessions. Multimodal approaches combining medication and non-pharmacological interventions should be explored to reduce pain and anxiety associated with painful procedures.

Innovation of non-pharmacological pain interventions. Studies and reviews have highlighted, in recent years, the effectiveness of multimodal approaches combining medication with non-pharmacological interventions for procedural pain relief. Distraction techniques have been recognized among the most effective non-pharmacological interventions. They divert the child's attention to an attractive element, hindering the perception of the painful stimuli and therefore reducing pain and anxiety. Distraction is based on the gate control theory of Melzack and Wall stating a link between perception of pain and level of attention devoted to the stimulus affecting the painful experience. Therefore, distraction techniques engaging multiple senses such as vision and audition may grab the child`s attention more than the techniques that only engage one sense. Hence, the increasing interest in more immersive and interactive methods of distraction such as virtual reality (VR) for the management of procedural pain.

Virtual reality distraction. This is an active distraction method that allows the user to interact with an immersive environment generated by a computer stimulating different senses (vision,

hearing and sometimes touch). VR allows a mental escape through multisensory interaction. Its effect is known to decrease pain and anxiety. In the past ten years, VR was tested through different studies with older children and adult burn victims. A study by Hoffman et al. in 2007, showed that the percentage of reduction in pain by VR was comparable to the reduction resulting from a moderate dose of hydromorphone equivalent to what a patient would receive during a burn wound care. Yet, the authors state that they believe the best analgesia is achieved by combining VR with pharmacological treatment. However, very few studies have tested the effect of a combination of pharmacological and virtual reality interventions, on procedural pain and anxiety of young children suffering from burn injuries. Also, current studies on VR mostly use 3D goggles or helmets in contact or close to the face of the child which could be challenging with young children since they mostly have burns on their face and upper trunk. Therefore, a new VR prototype has been developed in collaboration with the Society of Arts and Technology (SAT) in Montreal to provide an immersive interactive experience for the burn child in the hydrotherapy tank. The prototype was developed after several meetings between the researchers, the designers and engineers and the surgical-trauma team of CHU St. Justine. Meetings were followed by an ergonomic study of the hydrotherapy room to meet the unit's and patients' specifications and ensure that it doesn't interfere with the healthcare professionals work.

AIM

The aim of this pilot study is to assess the feasibility and applicability of the prototype as well as the satisfaction of the healthcare professionals regarding the use of the VR prototype for the relief of procedural pain and anxiety in young children with burn injuries.

Primary Research Question: In children from 2 months to 10 years old who have suffered burn injuries, is VR distraction a feasible, applicable and satisfactory method for pain relief during hydrotherapy? Secondary Research Question: In children from 2 months to 10 years old who have suffered burn injuries, does VR distraction provide better pain and anxiety relief during hydrotherapy than standard pharmacological treatment?

HYPOTHESES

a. VR distraction is a feasible and acceptable non-pharmacological method for procedural pain relief (during hydrotherapy) of young children with burn injuries.

b. VR distraction combined with analgesics is more efficacious than standard treatment (analgesics alone) on procedural pain and anxiety (during hydrotherapy) of young children with burn injuries.

METHODS

Design. Single-arm pilot study.

Sample and Setting. Participants will be recruited through convenience sampling upon admission to the surgical-trauma burn unit. The unit has a hydrotherapy room for inpatients and outpatients. Healthcare professionals usually present during hydrotherapy are: a burn wound care nurse, a nurse clinician from the pain clinic, an anesthetist, a physical therapist and an orderly. The size of the total desired sample is 15 to 20 participants depending on the recruitment rate since it is a pilot study. The study will take place in the hydrotherapy room of the CHU St. Justine, a large pediatric university teaching hospital in Montreal where the VR prototype is installed.

Eligibility criteria. Inclusion criteria: children from 2 months to 10 years old, with a burn injury, requiring a hydrotherapy session for burn wound care, and accompanied by a consenting parent/legal tutor who can understand, read, and write either French or English. Exclusion criteria: 1) Admitted to the intensive care Unit, 2) Neuro-cognitive disability that precludes children from interacting with the distraction intervention, 3) Unconscious or intubated during hydrotherapy session, 4) Suffering from epilepsy (considering the nature of the intervention), 5) Allergic to opioids or other analgesics used for standard pharmacological treatment.

Intervention: The child will visualize and interact with the virtual environment throughout the hydrotherapy session. VR prototype developed by the SAT will be used as the experimental intervention. It has a wide screen installed at the end of the hydrotherapy tank offering a 150-degree field view, on which appears a game allowing the child to have the immersive entertainment experience without the need to wear a helmet or 3D glasses. The child or a proxy, depending on age and burn site, will have the opportunity to interact with the game. The interactive component is not mandatory for the immersive and distractive experiences provided by the prototype. Video

games tailored to the child's age and injury, different from the commercially available ones, will be adapted to each age-group of children recruited with control over the speed of movement to avoid motion sickness.

Measures. Measures of baseline pain and anxiety will be recorded at T1, 30 minutes before the procedure, in the patient`s room. Measures for procedural pain, anxiety and sedation level will be taken at: T2, before the procedure, upon arrival in the hydrotherapy room, T3, during the procedure (10 min after the beginning of the hydrotherapy session), T4, immediately after the procedure before leaving the hydrotherapy room and T5, 30 minutes after the procedure in the patient`s room. The patient`s comfort level will also be assessed during the procedure at T3. Finally, the acceptability of the intervention will be assessed through a questionnaire comprising items on the acceptability and satisfaction of the healthcare professionals at T4. The same measures will be recorded for each participant for up to three hydrotherapy sessions. The primary outcome will be the acceptability of the intervention. Comparisons will be made between pain and anxiety levels for the same order of session.

A) Primary Outcome Measure: Acceptability [Time Frame: T4, immediately after the procedure before leaving the hydrotherapy room]: To assess the acceptability including the satisfaction of healthcare professionals regarding the use of the VR prototype during the hydrotherapy session. Pre-tested tailored questionnaire including satisfaction and acceptability outcomes (tolerance, positive and negative aspects, secondary effects).

B) Secondary Outcome Measures:

1) Pain intensity [Time Frame: T1, 30 minutes before the procedure (patient`s room); T2, upon arrival at the hydrotherapy room; T3, 10 min after the beginning of the hydrotherapy session; T4, immediately after the session before leaving hydrotherapy room; T5, 30 min. after the session]: Face, Legs, Activity, Cry and Consolability (FLACC).

2) Anxiety Level [Time Frame: T2, upon arrival at the hydrotherapy room; T3, 10 min after the beginning of the hydrotherapy session; T4, immediately after the session before leaving hydrotherapy room; T5, 30 min. after the session]: Procedure Behaviour Check List (PBCL).

3) Comfort Level [Time Frame: T3, during the procedure (10 min after the beginning of the hydrotherapy session)]: Behavioural observation scale of comfort level for child burn victims (OCCEB- BECCO).

4) Analgesic requirement [Time Frame: T3, during the procedure (10 min after the beginning of the hydrotherapy session)]: rescue dose medication administration.

5) Sedation level [Time Frame: T2, before the procedure, upon arrival in the hydrotherapy room, T3, during the procedure (10 min after the beginning of the hydrotherapy session), T4, immediately after the procedure before leaving the hydrotherapy room]: Ramsay sedation scale.

6) Baseline anxiety level [Time Frame: T1, 30 minutes before the procedure, in the patient`s room]: Modified Smith Scale.

FEASIBILITY

The setting of the study is the main referral center for pediatric burns in Quebec. It receives nearly 60 admissions during the period when there is a higher incidence of burns (April to October) and almost 100 admissions per year. The investigators will be able to access the population for the study given the PI's affiliation to the research center of this setting. Moreover, stakeholders in the pain clinic and surgical-trauma unit are aware of the study, and participated in all stages of the prototype development.

POSSIBLE PITFALLS AND SOLUTIONS

It is unknown whether the VR is a feasible distraction technique in young children/infants aged between 2 months and 2 years old. The pilot study will help inform the investigators about the visual tracking in infants during painful medical procedures. Upon completion of the pilot study, it will be decided whether to include or not the young population in the larger trial.

CONTRIBUTION AND EXPECTED RESULTS

Despite growing interest in the field, procedural pain management in children remains suboptimal and the importance of developing more effective methods is required. This project will provide

preliminary evidence on the feasibility, acceptability, and preliminary efficacy of non-pharmacological methods of procedural pain management through the development and testing of innovative interventions. VR distraction could be an interesting method to relieve pain, easy to use and without known side effects. The investigators hope that it could reduce the need for opioids and anxiolytics in burn children and decrease the pain related to the procedures while providing a less traumatizing hospital experience, which is often the first for children under 5 years old. The expected results have a direct effect on physical (pain, comfort) and psychological (anxiety) health of the child. In addition, clinical implications may include other indicators of quality of care and economic benefits such as duration of the hydrotherapy session, the amount of opioids and anxiety drugs administered, the use of coanalgesics, the number of professionals required in the hydrotherapy room and duration of wound healing.

DATA ANALYSIS PLAN

Descriptive statistics will be performed for sociodemographic and clinical variables, comfort levels and the satisfaction of health professionals. Non-parametric inferential statistics will be used to compare the mean differences in pain scores before, during and after the procedure as well as for anxiety and level of sedation. Since the use of rescue medication is a potential indication of a treatment failure, the analysis will be supplemented by an analysis comparing the proportion of patients receiving rescue medication anytime during the procedure. Interpretation of the analyses will be made with reference to the data regarding rescue medication use. Data collected on dichotomous variables will be analyzed using a chi-square test and post-hoc analyses if the results are statistically significant.