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Is Virtual Reality an Effective Tool for Reducing Procedural Pain in Pediatric Patients?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
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ABSTRACT

OBJECTIVE: The objective of this selective evidence-based medicine review is to determine whether or not, “Is virtual reality an effective tool for reducing procedural pain in pediatric patients?”

STUDY DESIGN: Included the review of three English language primary studies, published between 2014 and 2018. Articles were selected based on outcomes measured and relevance to the objective.

DATA SOURCES: PubMed was utilized to find two randomized controlled trials and one quasi-experimental study. The selected studies analyzed how the use of virtual reality impacted the amount of pain experienced by the pediatric patient undergoing either a venipuncture or burn wound care procedure.

OUTCOMES MEASURED: Patient outcomes were measured with the Faces Pain Scale – Revised (FPS-R), the Adolescent Pediatric Pain Tool and Word Graphic Rating Scale (APPT-WGRS) and the Visual Analogue Scale (VAS).

RESULTS: All three studies showed a statistically significant reduction in the level of procedural pain experienced by pediatric patients that utilized virtual reality while undergoing either a venipuncture or burn wound care procedure. The Gold et al. study showed a statistically significant reduction in procedural pain experienced with venipuncture vs. standard of care via the FPS-R. The Jeffs et al. study showed a statistically significant reduction in procedural pain experienced with burn wound care vs. passive distraction via the APPT-WGRS. The Piskorz et al. study showed a statistically significant reduction in procedural pain experienced with venipuncture vs. no virtual reality via the VAS.

CONCLUSION: The result of two randomized controlled trials and the one quasi-experimental study, which compared procedural pain in pediatric patients using virtual reality during venipuncture or burn wound care compared to a control group using either conventional standard of care, passive distraction or no virtual reality during the same type of procedure, showed virtual reality to be an effective tool for providing a statistically significant reduction in procedural pain in the pediatric patient population.

KEY WORDS: Virtual reality, Pain management, Effectiveness, Pediatric

INTRODUCTION

The procedure of phlebotomy has evolved immensely since the days of ancient Greece from which the word phlebotomy was derived. Historically, the term phlebotomy was formulated from a literal interpretation of the procedure, in which the word “tomia” meant “to lance” and “fleba” meant “a vein.”¹ Today the term phlebotomy has become synonymous with the term venipuncture, which is a more accurate description of the procedure of “blood draw” as we know it today. During modern day venipuncture, the wall of a vein is penetrated with a needle by a trained medical professional. Although the practice of phlebotomy has evolved drastically since the days of ancient Greece, there is still a considerable amount of pain associated with this common, yet invasive, childhood routine and emergency medical procedure.²

Procedural pain experienced during venipuncture first arises from the use of a tourniquet used to distend the veins. Intra-procedural pain occurs from the insertion of the needle into the vein while the blood sample is being collected. For pediatric patients, the smallest needle diameter should be selected to adequately penetrate the tiny, delicate veins of this patient population. Nonetheless, even with the smallest needle diameter, reactions associated with venipuncture in pediatric patients include crying, agitation, anger, uncooperativeness, aggression, increased breathing rate and increased heart rate.³

In addition to venipuncture, pediatric patients may also require medical treatment with more invasive procedures such as burn wound care. After the initial emergent management and stabilization of a pediatric burn patient, patients with severe burns may need to undergo burn wound care at a qualified burn center. The key elements of conservative burn wound management include cleansing the wound for visual inspection and debridement of any necrotic tissue that may be present. Additionally, topical antimicrobial agents may be applied to reduce

the occurrence of wound infection. Lastly sterile dressings are placed to protect the burn and to promote healing.⁴ In cases of severe burns, surgical intervention may be required.

Venipuncture and burn wound care are two examples of medical procedures in which a substantial number of children and adolescents experience procedural pain. The Friedrichsdorf et al. cross-sectional survey conducted at two United States Children's Hospitals found that seventy-six percent of one hundred and seventy-eight children interviewed had experienced pain during the past twenty-four hours of being hospitalized.⁵ In the same survey, forty-three percent of those that responded cited "needle pokes," such as venipuncture and intravenous access, as the most common reason for their pain.⁵ Additionally, a study conducted by the American Burn Association over a four year period found that twenty-four percent of the approximate four hundred and eighty six thousand patients treated for burn injuries in emergency departments across the United States were under the age of fifteen.⁶

Historically, virtual reality (VR) was a costly intervention, which limited VR research and the utilization of VR as a clinical intervention.⁷ Fortunately, with the ever-increasing accessibility and affordability of VR devices, the utilization of VR to create an immersive and calming VR environment to reduce procedural pain is now a practical and cost-effective option. Subsequently, children and adolescents are becoming increasingly proficient at utilizing advanced technology, which makes the utilization of VR to decrease procedural pain an attractive and feasible option for younger patient populations.⁷ It is proposed that inadequate pain relief experienced during painful medical procedures in childhood is likely to have a long-term negative impact on a child's future ability to respond to and tolerate pain.² Therefore, clinical trials evaluating the efficacy of VR as an effective tool for reducing procedural pain in the pediatric population are indicated.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not, “Is virtual reality an effective tool for reducing procedural pain in pediatric patients?”

METHODS

Studies were evaluated and selected based on their adherence to specific criteria including the age of the population studied and the type of procedural intervention used. Also, the measured outcome had to be a patient-oriented outcome, which mattered to the patient. Therefore, the studies selected for this systematic review needed to focus on a pediatric patient population receiving care for a medical procedure, such as venipuncture or burn wound care, in a pediatric medical setting. Also, a pain scale must have been administered post-procedurally to document the patient’s self-reported level of pain during the clinical procedure performed. Additionally, the comparison groups included in the studies were to include the pain management techniques of standard of care, passive distraction or no virtual reality.

The Cochrane Library was first used to ensure that a systematic review of this topic was not previously published. PubMed was then used to find two randomized controlled trials and one quasi-experimental study that were published in peer-reviewed articles and written in the English language. The keywords “virtual reality,” “pain management,” “effectiveness” and “pediatric” were used when searching for these scholarly articles. Ultimately, the articles that were selected were chosen based on their relevance to the objective of this systematic review. Inclusion criteria were clinical trials published after February 1, 2013. Exclusion criteria consisted of any scholarly articles that focused on any procedures other than a medical procedure. It is important to note that the Children’s Hospital of Los Angeles, where the

Gold et al. study was conducted, sees patients in their pediatric office up until the age of twenty-one. Therefore, the Gold et al. study extended the age range that they referred to as pediatric patients in the study to include participants up until the age of twenty-one years old.

The self-reported statistics of the patient procedural pain outcomes in the selected peer-reviewed articles were obtained using the Faces Pain Scale – Revised (FPS-R), the Adolescent Pediatric Pain Tool and Word Graphic Rating Scale (APPT-WGRS) and the Visual Analogue Scale (VAS), respectively. In this systematic review, the self-reported procedural pain data from each peer-reviewed article was analyzed individually. The statistical analysis involved the calculation of a mean difference between arms, CI, and/or corresponding p-value from continuous data. In this systematic review, the statistically significance threshold was $p \leq 0.05$. Table 1 provides a chart of the study demographics and characteristics of the three articles that were selected for this systematic review.

OUTCOMES MEASURED

The statistical analysis in the Gold et al. study utilized the FPS-R. The FPS-R is a self-reported pain measurement scale that uses photographs of facial expressions with the absence of smiles or tears in which the patient is asked to choose a face. The chosen face as read from left to right is then correlated with a score of 0, 2, 4, 6, 8 or 10 in which zero equals no pain and ten equals very much pain.⁸

The statistical analysis in the Jeffs et al. study utilized the APPT-WGRS. The APPT-WGRS is a self-reported pain measurement scale that consists of three components including: the outline of a human body on which areas of pain may be appropriately marked, a descriptive word list in which the patient may select words describing their quality of pain, and a 100 mm line in which a patient may mark the severity of their pain according to distance.³ For the purpose of the

Table 1. Table of the Characteristics and Demographics of the Peer-Reviewed Articles Selected for this Systematic Review

Study	Type	# Patients	Total Mean Age (years)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Gold, Mahrer ⁷ (2017)	RCT	143	15.43 with participants in both groups between the ages of 10 – 21 years old	Patients scheduled to receive a blood draw and were either English or Spanish speaking	Patients were excluded if they had cognitive disability or developmental delay, a history of seizure, currently taking pain or anxiety medications, had flu-like symptoms or had a visual or auditory impairment	0	Virtual reality head-mounted display with standard of care vs. standard of care alone
Jeffer, Dorman, Brown et al. ³ (2014)	Single-blinded RCT	28	13.5 with participants in both groups between the ages of 10 – 17 years old	Patients undergoing burn wound care as a first time visit or as a first time visit without conscious sedation	Patients were excluded if they had a history of motion sickness, seizure disorder, cognitive delay.	0	Virtual reality articulated arm-mounted vs. passive distraction
Piskorz, Czuby ⁹ (2018)	Quasi-experimental study with experimental group (VR) and control group (no VR)	38	Virtual Reality: 11.10 Control: 11.42 with participants in both groups between the ages of 7 – 17 years old	Patients staying at the clinic that had a blood draw scheduled	Exclusion criteria was not provided in this study	0	Virtual reality head-mounted display vs. no virtual reality

Brown et al. study, the results regarding the severity of procedural pain experienced by each participant focused on the distance marked on the 100 mm line in which 0 mm on the left indicated no pain and 100 mm on the right indicated the worst pain.³

Lastly, the statistical analysis in the Piskorz et al. study utilized the Visual Analogue Scale (VAS). The VAS is a self-reported pain measurement scale that uses a 10 cm continuous line in which 0 cm on the left indicates no pain and 10 cm on the right indicates the worst pain. The VAS results are then coded in millimeter to give a range from 0 mm indicating no pain to 100 mm indicating the worst pain.⁹

RESULTS

Of the selected peer-reviewed articles, two were randomized controlled trials and one was a quasi-experimental study. All studies excluded patients that were under that age of seven to ensure that the study participants would be able to use the VR equipment and to accurately complete the assigned self-report pain measurement questionnaires.

The Gold et al. study was a randomized controlled trial which looked at the efficacy of the intervention of VR plus standard of care (SOC) in the experimental group vs. the use of SOC alone in the comparison group for reducing acute procedural pain incurred from venipuncture. In this study, one hundred forty-three patients set up to receive outpatient phlebotomy at a pediatric hospital were offered and agreed to participate in the study. The patients in the study were randomized to receive either VR with SOC or SOC alone via a computer-generated randomization scheme controlled by an individual team of personnel.

In the Gold et al. study, the standard of care procedure involved a brief interaction with the phlebotomist to check patient identifiers, apply a tourniquet and perform an antiseptic prep. This initial interaction with the phlebotomist was then followed by the clinical procedure of completing the blood draw. Additionally, each patient in the standard of care comparison group was placed in a patient room that had a television playing a cartoon movie at a low volume during their venipuncture procedure.⁷

In the Gold et al. study, the participants in the experimental group received the same standard of care which consisted of interacting with the phlebotomist during their venipuncture procedure while a cartoon movie played at a low volume in the background. However, in addition, participants in the experimental group also interacted with a VR head-mounted display before, during and after their venipuncture procedure. These patients were immersed in a VR game environment for a total of approximately five minutes. Following the blood draw, the patients were asked to complete the Face Pain Scale- Revised (FPS-R) regarding the level of pain experienced during the venipuncture procedure.

The Gold et al. study analyzed the patient reported mean (M) standard deviation (SD) between the VR group (n = 70) and the SOC group (n =73) as shown in the table below. The difference between groups when comparing the effect of VR versus SOC on procedural pain experienced via the FPS-R, showed a M (SD) of -0.29 (.14). Additionally, a p-value < 0.05 validated this data as statistically significant data. The author did not supply a CI.

Table 2. Gold et al. Study Analyzed the FPS-R score M (SD) Between the VR vs. SOC Group

Gold et al. ⁷	Face Pain Scale – Revised Score M (SD)
SOC Group	1.70 (1.13)
VR Group	1.40 (.73)
Difference Between Groups	-0.29 (.14)

The Jeffs et al. study was a single-blinded randomized controlled trial in which the outcome data was collected by members of the study that had no knowledge of the participants group assignment. In this study, twenty-eight participants were enrolled and randomly assigned to VR or passive distraction (PD). This study evaluated the effectiveness of VR vs. PD at reducing procedural pain among children and adolescents undergoing one burn wound care treatment at an outpatient burn center.³

While undergoing their burn care procedure, the VR group participants were immersed into a VR environment via a tripod arm-mounted display. The participants in the PD group were given noise-canceling headphones to listen to and watch an age-appropriate moving during their procedure. It is important to note, that by intentionally utilizing the VR tripod arm-mounted display, the Jeffs et al. study was able to include participants with burns on their head. In both the Gold et al. study and Piskorz et al. study, a VR head-mounted display was specifically chosen so that either the left arm or right arm could be selected for the venipuncture procedure.

In the Jeffs et al. study, the estimated procedural pain scores obtained using the 100 mm line from the APPT-WGRS “were adjusted for age, sex, opioid analgesic use, treatment length and preprocedural pain.”³ In the Jeffs et al. study it was shown that the PD control group (n =10) reported an estimated procedural pain score of 52.4 mm while the VR experimental group (n = 8) reported an estimated procedural pain score of 28.7 mm. This resulted in a mean difference between arms of 23.7mm. Additionally, a p-value of 0.029 validated this data as statistically significant data. However, a wide 95% CI of 2.4 – 45.0 reflected the small sample size utilized in this study.

Table 3. Jeffs et al. Study Analyzed the APPT-WGRS Score (mm) in the VR vs. the PD Group

Jeffs et al. ³	APPT-WGST (mm)
PD Group	52.4
VR Group	28.7
Mean Difference Between Arms	23.7

The Piskorz et al. study was a quasi-experimental study consisting of a two-level independent variable, which included the presence or absence of VR distraction, and one dependent variable, which was the intensity of pain as measured by the visual analogue scale.

The participants in the VR group (n = 19) were immersed in a head-tracking VR environment whereas participants in the control group (n = 19) received no utilization of VR during their venipuncture procedure. The purpose of the Piskorz et al. study was to test the hypothesis that VR is an effective distraction tool to reduce procedural pain during a venipuncture procedure.⁹

In the Piskorz et al. study, a comparison of the pain experienced during venipuncture as collected by the self-reported VAS showed that the M (SD) was 37.05 (30.66) for the control group with no VR vs. a M (SD) of 15.16 (20.51) for the experimental group that was immersed in a VR environment during their venipuncture procedure. Thereby showing 59% less procedural pain experienced by the experimental group that were immersed in a VR during their venipuncture procedure.⁹ Additionally, a p-value of <0.02 validated this data as statistically significant data. The author did not supply a CI in this study.

Table 4. Piskorz et al. Study Analyzed the VAS Score M (SD) Between the VR group vs. the No VR Group

Piskorz et al.⁹	VAS M (SD)
No VR Group	37.05 (30.66)
VR Group	15.16 (20.51)
Difference Between Groups	59% Less Procedural Pain Reported in VR Group ⁹

DISCUSSION

The peer-reviewed articles discussed in this systematic review supported that VR is a statistically significant distraction tool for reducing procedural pain in pediatric patients over the age of seven. Each article demonstrated a statistically significant decrease in procedural pain experienced by participants using VR vs. the comparison group. However, additional clinical trials are needed to further evaluate the efficacy of utilizing VR in larger patient populations of a broader age range. Additionally, further clinical trials are needed to evaluate the use of VR for

reducing pain associated with a wider range of clinical procedures other than the medical procedures focused on in this systematic review.

An advantage of VR was highlighted in an interesting randomized controlled trial crossover study by McSherry et al. looking at eighteen adult patients undergoing painful wound care procedures. The McSherry et al. study showed a thirty-nine percent reduction in the amount of opioid medication administered to participants immersed in a VR environment during their wound care as compared to participants not immersed in a VR environment during their wound care procedures.¹⁰ With the United States currently in the midst of an unprecedented opioid epidemic, the need for non-pharmacological interventions for the reduction of pain is evident. Therefore, continued clinical trials evaluating VR as a means to negate or reduce the need for opioid pharmacological intervention during painful medical procedures is another direction deserving of attention. The utilization of VR has promise to reduce the undesirable effects experienced by opioid and non-opioid pain medications. However, the utilization of VR does not come without its own side effects or limitations.

One of the side effects of VR seen in the Gold et al. study was mild to moderate nausea that was reported by 5.2% of the patients utilizing VR in the study.⁷ This adverse side effect of VR had the potential to cause a negative impact on the amount of procedural pain experienced by these participants. However, none of the participants in the other studies reviewed reported any adverse side effects such as nausea from utilizing the VR equipment. Regardless, more clinical trials are needed to further evaluate all the potential side effects of VR utilization.

Lastly, it is important to note that the generalizability of the Jeffs et al. study reviewed in this systematic review was limited by the study design utilizing one small outpatient burn wound care center for its statistical analysis.

Therefore, further clinical trials looking at VR as an effective means for reducing procedural pain in a more expansive study of outpatient burn wound care centers should be developed. Furthermore, studies evaluating the efficacy of VR as an intervention for reducing procedural pain in participants undergoing invasive inpatient burn wound care should also be developed. Additionally, numerous participant variables should be considered in future studies.

Although expanding the number of locations examined in a study will assist in making the findings of study more generalizable. Careful consideration must be taken when deciding upon the inclusion and exclusion criteria from which to formulate a participant population. For example, when developing the inclusion and exclusion criteria for a new study design, factors such as the location or the depth of the burn being treated may be considered. However, such participant criteria must be carefully selected as to adequately support the objective of study while not being so stringent as to minimize the generalizability of the study.

CONCLUSION

Through this systematic review, virtual reality has been shown to be an effective tool for reducing procedural pain in pediatric patients. When compared to a control group, the two randomized controlled trials and the one quasi-experimental study in this systematic review exhibited statistically significant reductions in the amount of self-reported procedural pain incurred during either a venipuncture or burn wound care procedure. However, as addressed in the discussion section, further studies to support a generalized acceptance of VR as a distraction tool for reducing procedural pain should be developed. Additionally, the time required to properly sanitize the VR equipment and maintain VR software updates should be considered. Lastly, a plan should be developed of how to proceed if a technological malfunction of the VR equipment should occur while it is being utilized as a distraction tool.

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