

The Effect of Virtual Reality-Based intervention on pediatric pain and anxiety levels during Venipuncture procedure

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Abstract: Venipuncture is most distressing and painful needle-related procedure experienced by pediatric where distraction combined with age-appropriate could be reduce procedural pain and anxiety among children. Virtual Reality (VR) is new technique for distraction and powerful technology implemented in a healthcare setting. **Objective:** Guided by Gate Control Theory, the study aimed to evaluate the effect of VR intervention on the pain and anxiety levels of children during venipuncture procedure. **Method:** Children were assigned randomly to one of two groups: a control group receiving standard care and VR group receiving VR distraction plus standard care during procedure. Pain scores were assessed using the Wong-Baker Faces Pain Scale (W-BFPS) and the Visual Analogue Scale (VAS) and the state of anxiety was measured by Facial Affective Scale (FAS). The anxiety and pain levels were evaluated based on the self-report approach from participated children. **Results:** A total of 144 children were randomly assigned to VR and control groups (72 VR and 72 control). The baseline characteristics of the VR and control groups were comparable. The self-reported W-BFPS and VAS revealed that pain level felt by the VR group during venipuncture procedure was lower than the level of pain indicated by control group significant at $P < 0.031$; $P < 0.040$ respectively. The self-reported Facial Affective Scale for anxiety level showed a significant difference between the VR and control groups ($P < .001$). **Conclusion:** It was determined that using the (VR)headset significantly reduced the pediatric pain felt and level of anxiety during a venipuncture procedure.

Keywords: Virtual reality, pain management, distraction, non-pharmacological analgesia, children anxiety.

1. INTRODUCTION

Medical procedures can be negative experience that evoke pain, distress, and anxiety (Baeyer & Tupper, 2010) and particularly in children, these feelings not only emerge discomfort during medical procedures and with adverse consequences as poor recovery, sleeping disorders (Kain et al., 2006), and posttraumatic stress symptoms (Meentken et al., 2017). Moreover, pain and anxiety could give us indication for health care (Inal & Kelleci, 2012), where we needed to study pain and anxiety which give distraction combined with age-appropriate information which could decrease procedural pain and anxiety (Wong et al. 2019). Distraction is a commonly applied intervention during medical procedures (Inan & Inal, 2019) and Tousseau (2013) asserted that distraction is the best technique to refocus the attention of children away from pain and anxiety. VR is new method which provide a powerful technical that implemented in a healthcare setting with almost endless possible uses at low cost (Ashmore et al., 2019; Gupta et al. 2018), and enhanced experience of several sensory feedbacks (auditory, visual and tactile) that is increased (Cooper et al. 2018). In terms of clinical applications of VR, there is growing interest in the use of VR-based therapy in multidisciplinary symptom (Hoffman et al., 2014; Glennon et al., 2018). VR could be most efficient toll as complementary adjunct or alternative non-pharmacologic analgesic. Indovina et al. classify VR analgesia functions for acute pain extending such as dental treatment, pre and post-surgical procedures, e.g. mitigating pain under local anesthesia, and venipuncture in pediatric

patients (Indovina et al., 2018). The increasing affordability and quality of portable VR headsets and the ongoing utility of pain therapy (Ahmadpour et al., 2019; Chirico et al., 2016). It has been reported that the primary mechanism through which pain perception is attenuated is via distraction, although other non-distraction mechanisms have been proposed (Li et al., 2011; Gupta et al. 2018; Indovina et al. 2018). (VR)(VR) distraction is a psychology-based approach that is both immersive and interactive, which can distract attention from painful feelings by immersing children in a supportive computer-generated visual or auditory stimulation environment (Olk et al., 2014; Wiederhold et al., 2018). In general, a VR system uses a microprocessor, a three-dimensional screen head mounted and advanced built-in software to construct an interactive virtual environment (Birnie et al., 2018).

To date, few theories about the pain-attenuating effects of VR have been suggested beyond simple distraction. VR therapy includes multiple neuronal cortical and subcortical circuits that potentiate learning and recovery for patients (Ito & Doya, 2011; Solouki & Pooyan, 2016). Therapeutic (VR)(VR) has emerged as an effective, non-pharmacological tool for pain treatment (Dascal et al., 2017), but there is a lack of studies evaluate its effectiveness among hospitalized children. The current study aims to examine the efficacy of VR intervention in reducing pain and anxiety level during venipuncture among pediatric patients. Authors hypothesized that distraction from the VR and standard care would improve pain tolerance and anxiety level relative to baseline. However, we anticipated that VR-assisted distraction had a great analgesic effect.

1.1. Theoretical Background

The Gate control theory provide the theoretical framework of this study (Melzack & Wall, 1965). Based on the gate control theory, pain signals are not free to reach the brain as soon as they are produced in tissues or sites that have been damaged. They face some 'neurological gates' at the spinal cord and these gates decide whether or not the pain signals will enter the brain (Nizard et al., 2012).

In case of tissue damaged, peripheral nerves are activated, nerve impulses travel through spinal cord networks and neuroanatomic shapes before entering cerebral cortex where pain is felt. The gate control system in the spinal cord opens and closes to modulate pain perception (Wong et al., 2019). Based on the Gate control theory, VR will divert the children's attention from venipuncture-associated pain, accordingly helping close gate control and decrease pain perception (DeMore and Cohen, 2005; Wong et al., 2019).

2. MATERIAL AND METHODS

2.1. Design and Participants

This study is a prospective quazi experimental, consisting of two parallel groups. A total of 144 children were recruited to receive either standard care/distraction (control group) or VR distraction (Intervention group). Participants are being recruited from public hospital, Zagazig, Egypt. According to Piaget's theory, children aged 8–12 years belong to the concrete operational stage (Piaget, 1963) and children of the same stage perceive information and pain sensitivity similarly (Blankenburg et al., 2010). Therefore, children aged 8-12 years who underwent to venipuncture were included. Children were excluded if they have developmental delay, cognitive, visual or auditory impairments, were currently taking pain or anxiety medication

2.2. Study Measurements

2.2.1. Demographic data and clinical characteristics

Demographic data were collected from medical records and through parental queries. The demographic information questionnaire included questions regarding age, gender, level of education, required medical procedure, past medical history and other information.

2.2.2. Pain and Anxiety

Wong-Baker Faces Pain Scale (W-BFPS): is an instrument that was developed by Donna Wong and Connie Baker and it widely used to assess pain intensity.

The scale was developing for kids and used within aged 3 or more. For children could understand cartoon faces (Drendel et al., 2011; Hockenberry et al., 2015). W-BFPS shows a series of faces ranging from a smiling happy face at 0, or "no hurt", to a crying face at 10, which represents "hurts like the worst pain imaginable". The possible minimum score on the scale is 0, and maximum possible score is 10. Based on the faces and written descriptions, the child chooses the face that best describes their level of pain (Coté et al., 2009).

The Visual Analogue Scale for pain (VAS): It is a 10-cm straight line with the endpoints defining extreme limits such as 'no pain at all' with a score of '0' and 'pain as bad as it could be' with a score of '10' (Drendel et al., 2011). The practitioner asked children to mark his pain level on the line between the two endpoints. VAS was first used in psychology by Freyd in 1923.

Facial Affective Scale (FAS): The initial FAS was comprised of 11 figure reflecting different types of facial expressions. The scale has been tested for its psychometric properties and showed good validity and reliability (Cao et al., 2017). The faces ranked from 0–10 (0 = no anxiety, while 10 = highest anxiety) and the investigator ask the child to match one of the 11 facial expression with a numeric verbal rating scale (Figure 1).

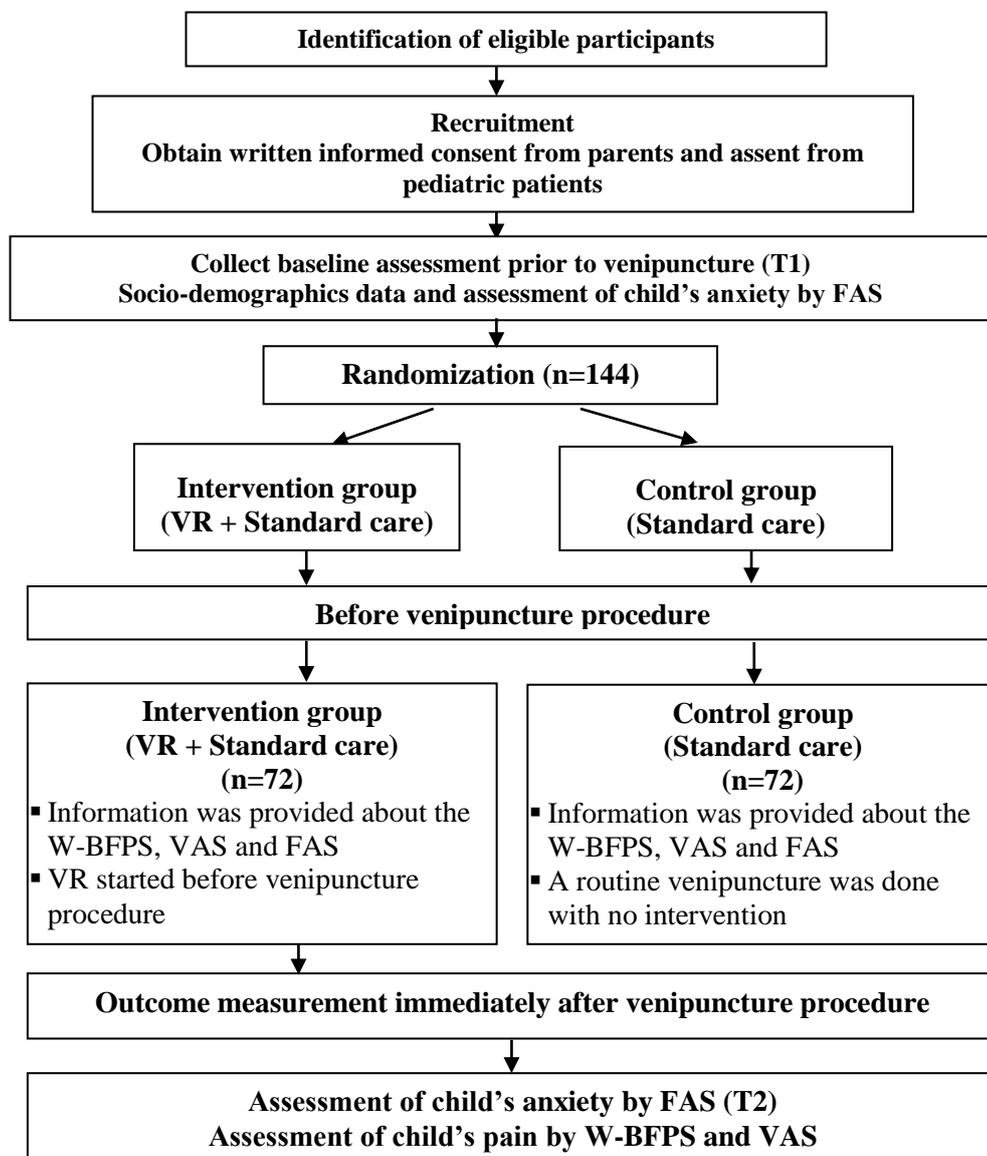


Figure 1. The study flowchart

2.3. (VR)Headset

Original 6.0 VR Headset version (Three Dimension Technologies) (VR)Glasses Stereo Headphones 3D Glasses Headset, Helmet support 4.7-6.0-inchlarge Screen and support Smartphone (with Controller SC-B01) with eye protector was used. The interocular distance can be adjusted for children and (VR)headset was tested on five children before being used and those who tested the VR headset were excluded from the study.

2.4. Implementation

Once it has established that the child met the eligibility criteria, such children and their parents were told about the study in details by the investigator and provide them with a copy of study information sheet. Children who accepted to participate in the study were split into two groups randomly by nurse/administrative staff outside the study equally to maintain a good balance of participants between the two groups. Prior to division of the two groups, the researcher read a standard script to explain the pain and anxiety measurements and children indicated that they understood how to use the measurements. Parents are encouraged to ask questions to guarantee full understand and guided step by step through "informed consent form". Verbal consent was obtained from children who agreed to participate in the study, as well as written consent from their parents. In addition to standard care, children of VR group were briefly instructed on how to use a headset in virtual reality. Children started to watch the 3D "Aquarium VR" application via the (VR)headset five minutes before the venipuncture procedure. This procedure lasted about 3 minutes, during which time the children did not take off the (VR)headset. Children of the control group received standard care (with no VR intervention) which includes explaining the procedure and saying supportive and comforting words during procedures. The same pain measurements (W-BFPS and VAS) were given to children of control group.

Adverse effect and Discontinuation

Dizziness and nausea are the potential adverse effects of engagement in (VR)(table1). Using VR headset but researchers instructed the parents if any effects occurred they are free to withdraw their children and discontinue the participation. No adverse effects were reported in both groups.

Table 1. Possible benefits and side effects of VR

Benefits	<ul style="list-style-type: none"> ▪ Provides distraction from pain ▪ Improves movement ▪ Promotes imagination ▪ Fosters sense of internal health locus of control ▪ Improves cortical repatterning (potentially)
Side Effects	<ul style="list-style-type: none"> ▪ Visually-induced motion sickness (dizziness, nausea) ▪ Collisions with nearby objects ▪ As with other media, risks social isolation ▪ In younger children, possible potential for "false memories"

Adopted from Won et al., 2017

2.5. Data analysis

Using SPSS Version 23 for data analysis and P <.05. Score of scale was sum of the classified items and cut-off limit used of pain either presence or absence.

2.6. Compliance with Ethical Standards

The procedure performed in study involving human participants were in accordance with the national research committee ethical standards and with the Helsinki Declaration of 1975, as revised in 2013. In addition to the approval of the Ethical Review Board, Zagazig University, Egypt (Code nr: 2018/9-12).Written permission from the hospital as well as signed informed consent forms from the parents after explaining the purpose of the study were obtained. The researchers were explained that participation was voluntary, participants could withdraw from the study at any time and personal information would be kept confidential.

3. RESULTS

3.1. Demographic and baseline characteristics of participants

This study enrolled one hundred forty-four children (boys & girls) that met inclusion criteria, of them, 72 children were randomized to receive routine care during medical procedures (control group) and 72 children were randomized to receive VR distraction during medical procedures (VR group). The study flow chart is presented in Figure 1 and the baseline demographic and clinical characteristics of children are presented in Table 2. The mean \pm SD of age of the VR group was 9.47 ± 1.3 years (range 8 – 12 years). A total of 86 children (59.7%) had previous hospitalization and the majority of participants (91.7% of control group and 65.3% of VR group) had previous pain experience.

Table 2: Sociodemographic and baseline characteristics of study participants

Variable	VR group (n=72)	Control group (n=72)
Age in years mean \pmSD	9.47 \pm 1.3	9.2 \pm 0.9
Gender, n (%)		
Male	45(62.5%)	43 (59.7%)
Female	27(37.5%)	29 (40.3%)
Previous hospitalization		
Yes	40 (55.6%)	46 (63.9%)
No	32(44.4%)	26 (36.1%)
Previous pain experience		
Yes	47(65.3%)	66 (91.7%)
No	25(34.7%)	6 (8.3%)
Primary diagnosis n (%)		
GIT	20(27.8%)	16 (22.2%)
ENT	15 (20.8%)	47(65.3%)
Orthopedic	3 (4.2%)	5(6.9%)
Cardiac	1(1.4%)	0 (0%)
Others	33(45.8%)	4(5.6%)
Mother education n (%)		
No formal education	12(16.7%)	12 (16.7%)
Primary education	15(20.8%)	17(23.6%)
Secondary education	13 (18.1%)	19 (26.4%)
University & higher	32 (44.4%)	24 (33.7%)

3.2. Pain assessment outcomes among different scales

The study finding compared the pain levels felt by children of VR group and control group by two scales; The Wong-Baker faces pain rating scale and Visual Analog Scale.; table 3 illustrated that the W-BFPS were 2.83 ± 1.28 for VR group and 4.36 ± 1.80 for control group. The pain levels on the W-BFPS were higher in the control group ($P < 0.031$). Score for VR and control on VAS pain scale as 2.56 ± 1.65 and 3.88 ± 1.83 respectively. Pain level was high on VAS (control) and this difference was statistically significant ($P < 0.040$). Figure 2 showed that mean scores of W-BFPS among VR group were distributed mostly (87.5%) between “0” (no pain) and “4” (pain a little more) while the most of control group (75%) their scores ranged between “6” (pain even more) and “10” (pain worst). Scores in VR judging by Wong-Baker faces pain rating scale declined than control (Figure 2).

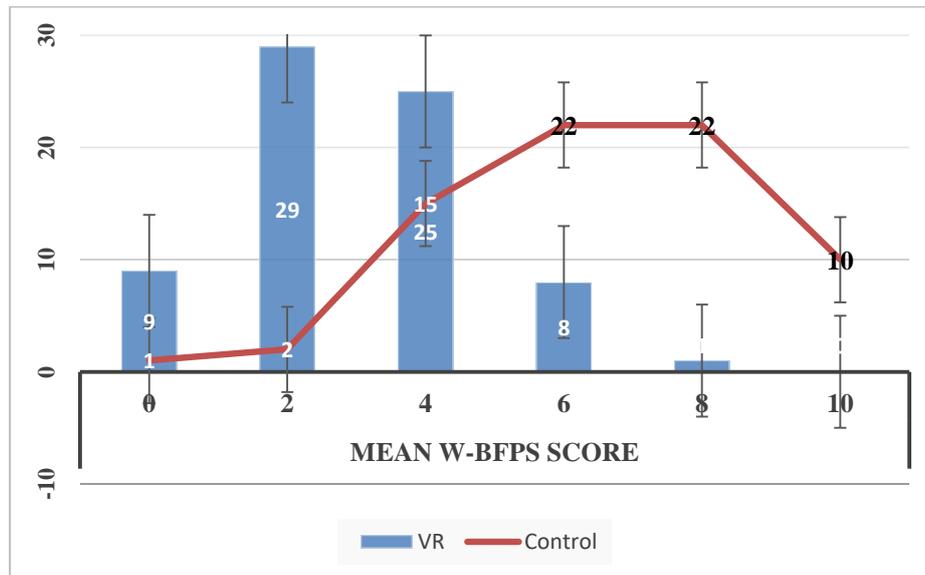


Figure 2: Comparison of W-BFPS-pain scores between VR group and control group

3.3. Anxiety assessment outcome

Table 4 presents descriptive statistics of child anxiety measured by the FAS at T1 and T2. The study results showed that children’s anxiety decreased over time (i.e. from baseline to post-induction, or T1 to T2) among the VR intervention group. In comparison, anxiety increased among children in the control group (Table 4). At post-induction, the mean FAS score for children’ anxiety in the intervention group was 0.76 ± 1.15 and 2.81 ± 1.67 for control group. This difference was statistically significant ($P < 0.001$).

Table 3. The Comparison of Pain Scores among participants during Venipuncture procedure

Measurement	VR group	Control group	P-value
W-BFS-Pain	2 (0-6)	4 (0-8)	0.031
	2.83 ± 1.28	4.36 ± 1.80	
VAS-Pain	2 (0-6)	4 (0-10)	0.040
	2.56 ± 1.65	3.88 ± 1.83	

Table 4: Comparison of children’ Anxiety Scores between groups indifferent time points (n = 144)

Group	Time	FAS Mean \pm SD	P-value
VR group (n = 72) Control group (n = 72)	T1	2.78 ± 1.17 2.69 ± 1.20	0.947
VR group (n = 72) Control group (n = 72)	T2	0.76 ± 1.15 2.81 ± 1.67	0.001

FAS=Facial Affective Scale; SD = standard deviation.

4. DISCUSSION

American Society for Pain Management Nursing said that, most appropriate pain control earlier than and through painful procedures should be provide and control acquired pain and resulting future anxiety (Sahiner and Bal, 2016). Variety of interventions were used for reduced pain and anxiety during medical procedures (Inan&Inal, 2019). The aim of the present study is to examine the efficacy of VR intervention in reducing pain and anxiety level during venipuncture among

pediatric patients. Results add to the growing body of literature that support the efficacy of distraction technique in general, and VR distraction in specific. The primary pain measurement technique remains self-assessment (Ngu et al., 2015) that is thought to be a reference when using the results of different assessment tools to explain pain intensity. Our findings are not unexpected when compared to previous studies that supported the efficacy of VR in reduction of pediatric pain and anxiety during painful medical procedures (Ding et al., 2019; Asl-Aminabadi et al., 2012; Gold and Mahrer, 2018). In the same context, Eijlers et al., conducted a systematic review study on EMBASE, MEDLINE, CENTRAL, PubMed, Web of Science, and PsycINFO databases. This study concluded that VR research in pediatrics has mainly focused on distraction and most of

The studies included indicates that VR is an important coping technique for pain and anxiety reduction in pediatric patients undergoing a wide variety of medical procedures (Eijlers et al., 2019). Conversely, there were number of studies indicated that no differences in self-reported pain during procedure (Sander et al., 2002; Gershon et al., 2004; Chan et al., 2007). It is vital to report that most of the participants received a topical cooling spray before the IV insertion. The VR used in this study is inexpensive, which may not be the most effective choice for pain relief for pediatric patients, however the efficacy was promising. With continuous hardware and software improvements, the application of VR in pain relief is likely to increase for pediatric patients undergoing to medical procedures in the future. There are some limitations that warrant discussion; first, blinding of the participants was not possible due to the nature of the study. Second, the FAS scores rely on participants' self-report measures and are thus, subjective. Therefore, objective measurements could be used in future researches. The final limitation that needs to be mentioned is that children were with their parent/relatives, which may have played a role in decreasing or raising their anxiety, and researchers were unable to determine this aspect, which should be taken into account when planning future studies.

5. CONCLUSION

This study examined the effects of (VR) on reducing the pediatric pain and anxiety during venipuncture procedure. It was determined that using (VR) headset significantly reduced the pediatric pain felt and level of anxiety during venipuncture procedure. Replicate this approach in more settings to give whether the findings are similar.

CONFLICTS OF INTEREST

Authors stated that there is no financial connection between them and any company having a direct interest in the topic or materials discussed in the article.

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AUTHORS CONTRIBUTION

All authors contributed to the concept of the research, design, collection data, analysis data, and preparation of manuscript

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HUMAN AND ANIMAL RIGHTS

The research procedure followed was consistent with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as updated in 2013.

DATA AVAILABILITY

Data supported by findings study available from corresponding author upon request.

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