

Is Virtual Reality Ready for Prime Time in the Medical Space? A Randomized Control Trial of Pediatric Virtual Reality for Acute Procedural Pain Management

Jeffrey I. Gold,^{1,2} PhD and Nicole E. Mahrer,² PhD

¹Department of Anesthesiology, Pediatrics, and Psychiatry & Behavioral Sciences, Keck School of Medicine, University of Southern California and ²Department of Anesthesiology Critical Care Medicine, Children's Hospital Los Angeles, Children's Hospital Los Angeles

All correspondence concerning this article should be addressed to Jeffrey I. Gold, PhD, Department of Anesthesiology Critical Care Medicine, Children's Hospital Los Angeles, 4650 Sunset Boulevard MS#12, Los Angeles, Ca 90027. E-mail: jgold@chla.usc.edu

Received May 3, 2017; revisions received September 26, 2017; accepted September 29, 2017

Abstract

Objective To conduct a randomized control trial to evaluate the feasibility and efficacy of virtual reality (VR) compared with standard of care (SOC) for reducing pain, anxiety, and improving satisfaction associated with blood draw in children ages 10–21 years. **Methods** In total, 143 triads (patients, their caregiver, and the phlebotomist) were recruited in outpatient phlebotomy at a pediatric hospital and randomized to receive either VR or SOC when undergoing routine blood draw. Patients and caregivers completed preprocedural and postprocedural standardized measures of pain, anxiety, and satisfaction, and phlebotomists reported about the patient's experience during the procedure. **Results** Findings showed that VR significantly reduced acute procedural pain and anxiety compared with SOC. A significant interaction between patient-reported anxiety sensitivity and treatment condition indicated that patients undergoing routine blood draw benefit more from VR intervention when they are more fearful of physiological sensations related to anxiety. Patients and caregivers in the VR condition reported high levels of satisfaction with the procedure. **Conclusion** VR is feasible, tolerated, and well-liked by patients, caregivers, and phlebotomists alike for routine blood draw. Given the immersive and engaging nature of the VR experience, VR has the capacity to act as a preventive intervention transforming the blood draw experience into a less distressing, potentially pain-free routine medical procedure, particularly for pediatric patients with high anxiety sensitivity. VR holds promise to reduce negative health outcomes for children and reduce distress in caregivers, while facilitating increased satisfaction and throughput in hectic outpatient phlebotomy clinics.

Key words: blood draw; pediatric; procedural pain; virtual reality.

Introduction

Virtual reality (VR) is quickly emerging into popular culture and is being highlighted as a transformative advent with a wide array of applications. Historically, VR has been cost-prohibitive for research trials and clinical interventions and impracticable/nongeneralizable

because of limitations in software development and hardware availability. The new generation of VR head-mounted displays (HMDs) has become a common technology, available off the shelf, reasonably priced, and user-friendly for a wide age range. The demographic for VR has thus shifted from a narrow group of

laboratory-based researchers or entertainment technologists to anyone with a smartphone or a game console. This opens the application of VR for wider use, including clinical application within a pediatric health-care setting. Given a heightened interest in preventive care and cost saving around health and wellness, and the concern about opioid addiction, VR may be perfectly suited for pain management.

VR technology was historically recognized for its entertainment value or exclusively applied and tested in academic experimental research laboratories (Bailenson et al., 2008). However, as VR moves from the bench to the bedside, its application has expanded to a variety of clinical areas. In medical settings, earlier versions of VR have been evaluated as a means to attenuate pain perception, anxiety, and general distress during painful medical procedures, such as wound care, chemotherapy, dental procedures, and routine medical procedures (Furman et al., 2009; Gold, Kant, & Kim, 2005; Gold, Kim, Kant, Joseph, & Rizzo, 2006; Morris, Louw, & Grimmer-Somers, 2009; Schneider, Kisby, & Flint, 2011), thus paving the way for the study of the more innovative and cost-effective VR technologies now entering the market.

VR is a state-of-the-art technologically advanced system that allows users to be fully immersed in a “virtual world” through a multimodal sensory experience (e.g., visual; auditory; tactile). This highly immersive and multisensory VR experience is therefore distinct from common forms of distraction (i.e., bubbles; books; toys) or passively watching television or movies, or playing a two-dimensional handheld video game or game console. Increasing access to VR technology and new software adaptations may prove to be a well-suited preventive intervention for painful medical interventions. VR draws heavily on the limited cognitive resource of attention, by drawing participants’ attention away from “real world” stimuli and into the “virtual world” (Hoffman, Patterson, Carrougner, & Sharar, 2001). Given the unique demand VR places on conscious attention, it is particularly well suited to reduce pain, and is one of the evidence-based strategies for pain management (see Mahrer & Gold, 2009; Malloy & Milling, 2010; Li, Montañó, Chen, & Gold, 2011 for reviews of the efficacy of VR for pain reduction). Previous research has supported the effectiveness of distraction during painful procedures, specifically needle pain (Birnie et al., 2014; Cohen, Cousins, & Martin, 2014; Goodenough et al., 1997; Maclaren & Cohen, 2005; Mason et al., 1999). VR, an arguably more powerful and immersive intervention, may be more effective than distraction at reducing pain and anxiety during painful medical procedures via a combination of attentional demands and other endogenous cortical systems.

To understand the underlying mechanistic origin for VR analgesia, investigators have considered the neurobiological interplay of brain cortices and neurochemistry, as well as emotional, cognitive, and attentional processes. While VR has been demonstrated in a variety of settings to effectively decrease pain and distress associated with painful procedures, researchers have only recently begun to identify neurobiological mechanisms underlying the effect of VR on the experience of pain, though previously accepted theories related to pain and attention likely apply. Gold and colleagues (Gold, Belmont, & Thomas, 2007) hypothesized that VR analgesia originates from intercortical modulation among signaling pathways of the pain matrix through attention, emotion, memory, and other senses (e.g., touch, auditory, and visual), thereby producing analgesia (Gold et al., 2007). They theorize that an overall decrease of activities in the pain matrix may be accompanied by increases of activity in the anterior cingulate cortex and orbitofrontal regions of the brain. While there is no singular theory that contextualizes the mechanisms of action for VR, preliminary research supports the phenomenon of VR analgesia with decreased functional magnetic resonance imaging (fMRI) bold signals in the pain matrix, in conjunction with decreased subjective reports of pain and anxiety, in response to thermal pain (Hoffman et al., 2004). Gold and colleagues (Gold, Chen, Katz, & Nelson, 2010) have further demonstrated that VR reduces pain signaling in the pain matrix, while increasing fMRI bold signal in brain regions associated with executive function (i.e., precuneus) associated with descending pain modulatory circuitry, during the experience of thermal pain (Gold et al., 2010). This descending modulatory circuit is an “opioid-sensitive” circuit and relevant to experiences in many contexts, including in states of chronic pain, and in the actions of pain-relieving drugs, including opiates, cannabinoids, nonsteroidal anti-inflammatory drugs and serotonin/norepinephrine reuptake blockers that mimic, in part, the actions of opiates (Ossipov et al., 2010).

VR and Nonvenipuncture

Numerous studies have consistently demonstrated the efficacy of VR for decreasing pain, distress, and anxiety, and reducing time spent thinking about pain during burn management and wound care (Das et al., 2005; Hoffman et al., 2000; Hoffman et al., 2008). Additionally, it was found that analgesia coupled with VR was more effective in reducing pain and distress than analgesia alone (Das et al., 2005). Earlier studies have also shown that VR can reduce the experience of pain (Schneider & Workman, 2000; Wint, Eshelman, Steele, & Guzzetta, 2002), physiological arousal (Gershon, et al., 2004), and procedure time (Schneider, Prince-Paul, Allen, Silverman, & Talaba,

2004; Schneider, et al., 2011) during common painful cancer treatments, such as chemotherapy infusions, lumbar puncture, and port access.

VR and Venipuncture

Venipuncture is an example of a common medical procedure that is routinely requested by doctors, and yet, often experienced as painful and distressing for children and adolescent patients (Fradet, McGrath, Kay, Adams, & Luke, 1990; Jacobson et al., 2001). To date, several small studies and few randomized controlled trials (RCTs) have supported the theoretical foundation intimating promise for VR as a particularly effective nonpharmacological method of pain management during venipuncture procedures. One study examined the effect of using nonimmersive VR compared with standard of care (SOC) during a needle-related procedure on reported pain or distress of children and adolescents in a pediatric oncology unit and found that though there were no significant differences in pain or distress, children enjoyed the nonimmersive VR and were distracted during the venipuncture procedure (Nilsson, Finnström, Kokinsky, & Enskär, 2009). Gershon et al. (2004) compared the effects of immersive VR, nonimmersive VR, and no distraction during port access on pain and anxiety in child and adolescent patients. Children in immersive VR had significantly lower heart rates compared with the control group, while children in both immersive and nonimmersive VR received significantly lower nurse ratings of pain, but not self-report. Gold et al. (2005) investigated the use of VR distraction during pediatric outpatient blood draw, comparing pain and anxiety in four conditions: no distraction, cartoon distraction, VR via computer, or VR via HMD. Children in the VR HMD group reported a lower frequency of moderate-to-severe pain intensity levels compared with the other three groups. No significant differences were found in average pain intensity and state anxiety between the four conditions. Gold and colleagues (Gold et al., 2006) also compared VR with SOC (topical anesthetic) in children requiring intravenous placement of contrast for a magnetic resonance imaging CT scan. While children in the control condition had a fourfold increase in pain, children in the VR condition reported no significant changes in pain intensity between preintravenous and postintravenous placement. Furthermore, children, caregivers, and nurses were more satisfied with the use of VR for pain management during the procedure.

Early work in VR using older technology and preliminary evidence has demonstrated VR's ability to reduce pain/distress in children and adolescents undergoing painful medication procedures. However, additional RCTs with newly developed VR technology and larger samples sizes are needed. Furthermore, it is

important to include a multimodal assessment of the patient's demographic and disease characteristics to more thoroughly understand the patient's experience within the virtual gaming environment and to determine which patients benefit most from VR intervention. The current study used a randomized control trial (RCT) to examine the feasibility and efficacy of VR compared with SOC for reducing pain and anxiety in children and adolescent pediatric patients (10–21 years) undergoing blood draw. It was hypothesized that patients playing VR would experience significantly less pain and anxiety, and improved satisfaction according to patient, caregiver, and phlebotomist report. The study also examined individual patient characteristics to identify types of patients that benefit most from the VR intervention. The study used state-of-the-art VR technology in hopes to increase patient's sense of presence within the virtual environment and increase the immersive-nature of the distraction. Preventing pain and anxiety during blood draw with VR has several important clinical implications including the prevention of future phobias related to medical interventions (e.g., needle phobia), medical trauma (i.e., posttraumatic stress disorder), improved patient cooperation with medical staff, and improved patient experience, thus leading to better child health outcomes.

Materials and Methods

Participants

The current study includes data from 143 child and adolescent patients (50.3% female; M (SD) age = 15.43 (3.13) years), their caregivers (mothers, fathers, and legal guardians) when patients were >18 years old, and their phlebotomists from the Children's Hospital Los Angeles, Department of Pathology, a nonprofit pediatric, urban, university-based academic teaching hospital. Caregivers included 87 mothers (61%), 17 fathers (12%), and 3 other legal guardians. Thirty-six patients (25%) were >18 years old. Patients were eligible if they were scheduled to receive a blood draw, were between the ages of 10 and 21 years, and were English or Spanish speaking. Patients were excluded if they had a cognitive disability or developmental delay, a history of seizure, were currently taking pain or anxiety medication, had flu-like symptoms, or had a visual or auditory impairment that would interfere with their ability to use VR according to patient and caregiver report. The current sample is consistent with the hospital population in regard to ethnicity and medical status (Table I).

Procedures

Study personnel approached patients and their families in the phlebotomy waiting room to determine interest and eligibility. Informed consent/assent was

Table I. Demographic Information

Variable	Total (N = 143)	VR (n = 70)	SOC (n = 73)	Total (N = 143)	
	M (SD)/%	M (SD)/%	M (SD)/%	T/ χ^2	p-value
Gender				0.345	.557
Female	50.34	47.14	52.05		
Male	49.66	52.86	47.95		
Age	15.43 (3.13)	15.79 (3.00)	15.06 (3.23)	-1.37	.173
Grade	9.71 (2.60)	10.00 (2.81)	9.43 (2.38)	-1.10	.27
Ethnicity				9.97	.126
Latino/a	60.0	63.77	56.06		
Caucasian	20.7	11.60	30.30		
Asian/Pacific Islander	8.1	10.14	6.06		
African-American	3.0	4.35	1.51		
Biracial/multiracial	4.4	4.35	4.55		
Other	3.7	5.80	1.51		
Medical condition				0.000	1.00
Yes	39.7	39.71	39.71		
No	60.3	60.24	60.24		
Number of previous blood draws	3.68 (6.08)	4.46 (7.41)	2.79 (3.93)	-1.53	.130

obtained from participants and their caregivers when the patient was a minor. Following consent, patients and their caregivers (when applicable) completed baseline measures about demographics and preprocedural pain and anxiety (~5–10 min). Using a parallel group design, patients were then stratified by gender, and randomly assigned using a computer-generated randomization scheme to one of two conditions: (1) SOC or (2) SOC plus VR during their blood draw. Study personnel were blind to patient condition until after the baseline measures were completed (i.e., study personnel checked the condition on a document stored in a separate folder and then assigned participants to their condition). No study personnel involved in recruitment or assignment were involved in generating the randomization scheme. Patients in the VR condition received SOC and interacted with the VR game a few minutes before, during, and following the blood draw procedure (~5 min total). Patients in the SOC condition received their blood draw according to SOC procedures only. SOC procedures involve brief interaction with the phlebotomist before the blood draw (i.e., asking for the patient's birthdate and prepping for the procedure, followed by the blood draw). Each patient room has a television playing a cartoon movie at a low volume. Following the blood draw, patients, caregivers, and phlebotomists were asked to complete postprocedure measures about pain and anxiety during the procedure as well as satisfaction with the procedure/VR when applicable (~5–10 min). The hospital's institutional review board reviewed and approved all study procedures.

Virtual Reality

Patients assigned to the VR condition engaged with the VR game Bear Blast (appliedVRTM) using the Samsung

Galaxy S6 mobile-based Gear VR goggles (ages 13–21 years) or the Google Pixel mobile-based Merge VR goggles (ages 10–12 years). Different VR goggles were used for older and younger age groups based on the safety requirements outlined in the user's manuals. In the multisensory (visual and auditory) immersive Bear Blast game, users travel on a preset path through a colorful, vibrant, highly interactive environment, filled with toy-like trees, mountains, rainbows, mushrooms, and bushes. As they gaze, they control the direction of a continuously firing cannon, which interacts with items in the world and positively reinforces experimentation and activity. They automatically enter a new level every 2.5 min, keeping the environment continuously fresh. Throughout the world, bears play the role of antagonist, standing in for the nuisance and distraction of pain. The VR game is equipped with a head-tracking system, enabling the player to look around the virtual environment, controlling the game with only movement of their head. Following the completion of every VR session, the removable face pad was replaced and the goggles and headsets were wiped down with alcohol-based sanitary wipes. Preventing infection via the sharing of the technology was a paramount issue with the study patients.

Measures

Demographics

Caregivers or patients ≥ 18 years completed a demographic form, which gathered information about age, grade, gender, ethnicity, medical diagnosis, and number of blood draws received in the past year.

Pain and Anxiety

Patients and caregivers completed a Visual Analogue Scale (VAS) and Colored Analogue Scale (CAS)

ranging from 0 indicating “no pain” to 10 indicating “worst pain” to report on pain intensity preprocedure and postprocedure. Both also completed the Faces Pain Scale-Revised (Hicks et al., 2001) to measure affective pain (worry and bother related to pain) preprocedure and postprocedure. Anxiety was measured by patients and caregivers preprocedure and postprocedure using the VAS for anxiety and the Facial Affective Scale (FAS; McGrath et al., 1985).

Anxiety Sensitivity

Patients reported on their anxiety sensitivity using the Childhood Anxiety Sensitivity Index (CASI; Silverman, Fleisig, Rabian, & Peterson, 1991) preprocedure ($\alpha = .86$). The 18-item measure uses a three-point Likert scale (none, some, a lot) to rate how negatively patients view anxiety symptoms (e.g., “It scares me when my heart beats fast”). Items are summed with a higher score indicating greater anxiety sensitivity. Previous studies have supported the reliability and validity of the CASI (Muris, Schmidt, Merckelbach, & Schouten, 2001; Silverman et al., 1991).

Satisfaction

Postprocedure, patients in the VR condition completed the investigator-developed Child Presence Measure to assess the degree of immersion in the game (Likert scale 1 “No,” 2 “A little,” or 3 “A lot”; score range 0–32). The 12-item measure asked children to respond to items related to three content domains: sense of involvement, perceived realism of VR game, and sense of transportation into the experience. Patients in the VR condition completed a Malaise Scale (Likert scale 1 “No nausea” to 6 “Sick”) to measure simulator sickness related to the VR game. Patients and their caregivers in both conditions also completed an investigator-developed Satisfaction questionnaire to assess satisfaction with the blood draw procedure, with the VR intervention if applicable, and solicit qualitative feedback. Phlebotomists also completed a five-item investigator-developed questionnaire postprocedure that asked about patient pain, anxiety, cooperation, and whether the phlebotomist was interested in using VR with their patients in the future.

Statistical Analyses

Power Analyses

Power analyses based on preliminary data determined that at least 100 participants were needed to have 80% power to detect a medium-sized effect on pain and anxiety outcomes. The sample size was increased 40% to include the covariates of baseline pain/anxiety in each regression analysis and allow for detection of a smaller-sized effect.

Patient Flow

Patients, caregivers, and phlebotomists were recruited for the study from May 2016 to June 2017. Recruitment was concluded once a sample size with sufficient power to detect a medium-sized effect was obtained. As shown in Figure 1, of the 303 patients screened for study participation, 15% did not meet criteria and 36% declined to participate. The most common reasons for declining participation were related to lack of time. In total, 146 patients (48% of those eligible) were randomized to condition, and 143 patients (47%) had complete data and were included in the analyses.

Preliminary Analyses

Descriptive statistics were used to characterize the study sample. *T*-tests and chi-squared analyses were used to compare demographic variables by condition. Bivariate correlations examined the relations between demographic variables (age; gender; number of past procedures) and anxiety sensitivity with the postprocedure pain and anxiety variables according to patient-report. Qualitative data about patient, caregiver, and phlebotomist satisfaction with VR, as well as immersion and simulator sickness are also presented.

Primary Analyses

Controlling for baseline pain/anxiety, linear regression analyses examined how condition (SOC vs. VR) predicted patient postprocedural pain/anxiety according to patient and caregiver report. Secondary analyses examined the moderating role of demographic or anxiety sensitivity variables found to be significantly related to postprocedure variables. Specifically, controlling for baseline pain/anxiety, linear regression analyses examined how condition (SOC vs. VR), the moderating variable, and the interaction between condition and the moderator, predicted postprocedure pain/anxiety according to patient report. Significant interactions were probed for further interpretation. *T*-tests compared phlebotomist-report of patient pain, anxiety, and cooperation during the blood draw in VR versus SOC conditions.

Results

Preliminary Analyses

Descriptive statistics about demographic data and study variables are presented in Tables I and II, respectively. There were no significant group differences in age, grade, gender, number of previous blood draws, or ethnicity (all *p*-values $> .12$; Table I). Bivariate correlations showed that gender (coded 0 = female, 1 = male) was significantly related to procedural pain (as measured by the Pain VAS and Faces Pain Scale-Revised; $r = -.22$, $p < .05$ and $r = -.25$, $p < .01$),

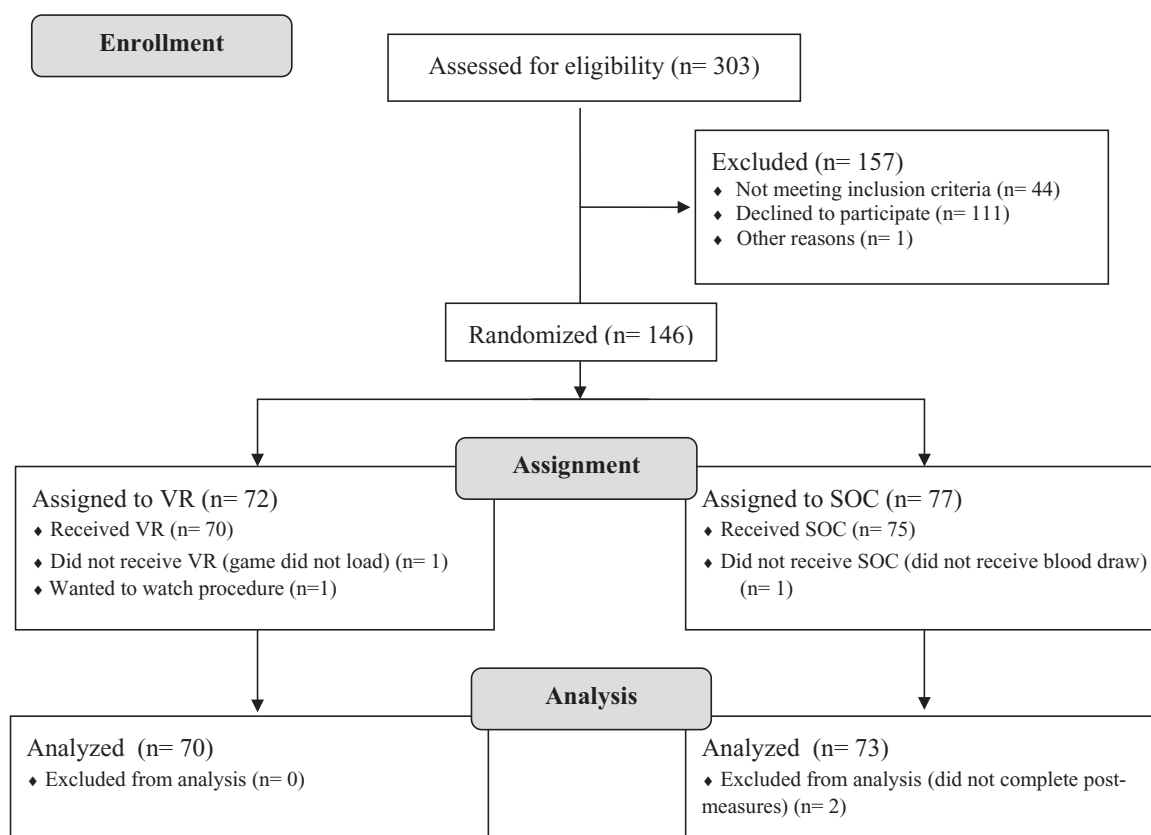


Figure 1. Patient flow diagram.

Table II. Descriptive Statistics on Study Variables by Report and Condition

Measure	Patient-report M (SD)		Caregiver-report M (SD)	
	VR (n = 70)	SOC (n = 73)	VR (n = 52)	SOC (n = 49)
Pain VAS	1.31 (1.59)	1.93 (2.22)	1.06 (1.72)	2.26 (2.68)
Pain Color Analogue Scale	1.58 (2.02)	2.00 (2.10)	1.19 (1.57)	2.29 (2.38)
Faces Pain Scale—Revised	1.40 (.73)	1.70 (1.13)	1.54 (.88)	2.02 (1.30)
Anxiety VAS	1.90 (2.22)	2.48 (2.07)	1.52 (2.03)	2.48 (2.63)
FAS	0.28 (0.22)	0.40 (.24)	0.33 (0.22)	0.38 (0.25)

FAS = Facial Affective Scale; VAS = Visual Analogue Scale.

anxiety (as measured by the Anxiety VAS; $r = -.18$, $p < .05$), and affect (as measured by the FAS; $r = -.24$, $p < .01$). Age was significantly related to procedural pain (as measured by the Pain VAS, $r = -.20$, $p < .05$; Pain CAS, $r = -.17$, $p < .05$; and Faces Pain scale, $r = -.21$, $p < .05$). Anxiety sensitivity significantly related to higher procedural anxiety (Anxiety VAS, $r = .20$, $p < .05$). Grade, ethnicity, and number of previous blood draws were not significantly related to any procedural pain or anxiety variable according to patient-report.

In terms of satisfaction with the VR game, patients reported high levels of immersion (M (SD) = 22.75 (6.32). In total, 92% of patients in the VR condition reported no simulator sickness. Four patients (5.2%) reported mild to moderate nausea during the VR

game. Beyond simulator sickness, no other adverse events were reported. Phlebotomists reported that they thought that the VR helped and that they wanted to use VR with other patients 98% of the time. One patient in the VR condition reported that the VR “keeps your mind busy and away from the needle. It made it easier and faster.” Another patient explained that he was “nervous at the idea of blood draw, however the VR game truly helped distract [him] from the feeling of the needle being inserted.” One caregiver stated that he “[wished his son] could do this every time he has a blood draw. He actually smiled coming out.” Another caregiver explained that she “[likes] it because [she thinks] that kids focus not on the blood draw/needle, but focus on the game. They forget about the needle.”

Primary Analyses

Controlling for baseline levels, patients in the VR condition experienced significantly less procedural pain (as measured by the Pain VAS), procedural anxiety (as measured by the Anxiety VAS), and had significantly better affect (as measured by the FAS) during the blood draw procedure compared with the SOC condition according to both patient and caregiver-report (small, but practically significant effects; Ferguson, 2009; Table III). Secondary analyses examined the potential moderating role of VR goggle-type, age, gender, number of previous blood draws, and anxiety sensitivity based on the significant correlations. Regression results demonstrated a significant interaction between anxiety sensitivity (as measured by the CASI) and condition in predicting patient procedural anxiety (b (SE) = $-.13$ (.05), β = $-.46$, p = .006; a moderate effect; Ferguson, 2009). Probing the interaction showed that when anxiety sensitivity was low (1 SD below the mean), there was no significant difference in anxiety between groups (b = .015, β = .004, p = .97). However, when anxiety sensitivity was high (1 SD above the mean), patients in the VR condition experienced significantly less anxiety compared with SOC (b = -1.66 , β = $-.39$, p < .001; Figure 2). This finding suggests that patients with high anxiety sensitivity benefit more from the VR intervention. VR goggle-type, age, gender, and number of previous blood draws did not significantly moderate effects of VR during blood draw on any procedural pain or anxiety variables according to patient report (all p -values > .14). There were no significant differences by condition in procedural pain, anxiety, or cooperation according to phlebotomist-report (all p -values > .16).

Discussion

The current project is the largest RCT of VR versus SOC in pediatric pain management. This trial marks the first RCT examining the new generation of VR technology on a defined population of children undergoing blood draw, and a game designed to assist patients with pain and anxiety management during painful medical procedures (Bear Blast by appliedVR™). Additionally, this study uniquely gathered qualitative information about pain management satisfaction from the patient, the caregiver, and the phlebotomist. Finally, the current study is the first VR RCT to examine the moderating influences of patient characteristics on the effects of VR. Given the public's excitement and enthusiasm for VR and its applications, specifically in health care, this article marks a critical first step in the examination of the new generation of VR technology for acute procedural pain management.

The proposed hypotheses were supported by the data, consistent with previous research examining VR in burn care (Das et al., 2005; Hoffman et al., 2000;

Hoffman et al., 2001) and during routine medical procedures (Gold et al., 2006). Patients randomized to VR experienced significantly less pain and anxiety, and significantly better affect, as measured by patients and caregivers, compared with SOC. VR was more effective for children with higher anxiety sensitivity. Specifically, children using VR who were more distressed by physiological feelings of anxiety, experienced significantly less anxiety compared with those patients with lower anxiety sensitivity or receiving SOC. Patients reported high levels of immersion associated with the Bear Blast and few reported any negative side effects, such as simulator sickness or nausea. Patient, caregiver, and phlebotomist satisfaction scores demonstrated that all three groups recognized the value in VR, reported high levels of satisfaction, would consider using VR again, and would recommend that other patients try VR.

The current findings suggest that VR is not as straightforward and simple as investigators and clinicians have believed. Individual differences and patient characteristics do appear to impact the effects of VR on pain perception/experience as a function of anxiety sensitivity. The complex nature of VR for attenuating pain during a routine medical procedure, blood draw, does appear to be influenced specifically by factors not previously explored in the early VR studies. In support of previous research examining the effects of VR on physiological arousal (Gershon, et al., 2004), it appears that patients with the greatest amount of anxiety sensitivity, in particular discomfort with symptoms of physiological arousal (e.g., increased heart rate), benefit the most from the VR intervention. This contribution begins to delineate some of VR's unique contributions to reducing pain and overall distress/anxiety. While the current study supports the efficacy of VR across age, gender, and previous experience with blood draw during blood draw, future VR research will continue to benefit from the investigation of patient (age; gender; ethnicity), disease (numbers of procedures; medication; diagnosis), and environmental (virtual environment; immersion) characteristics that may alter the benefit of VR and that are unique to the population of study and the types of virtual environments used to improve patient health outcomes.

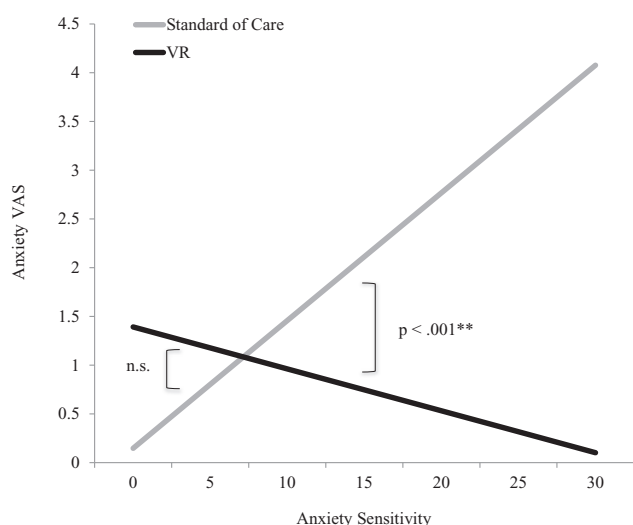
Patient satisfaction has recently become a beacon and driving force for examining clinic/hospital clinical performance and identifying clinical excellence. As such, VR may be uniquely positioned to influence both the patient and the patient's caregiver's experience/satisfaction with overall health care, while decreasing common anxieties and pain/fears associated with blood draw or other routine medical procedures. Additionally, health-care provider satisfaction is critical in patient outcomes, minimizing job burnout, fatigue, and compassion fatigue, resulting in low turnover, and overall job satisfaction (Kalliath & Morris, 2002).

The field of VR, although gaining tremendous popularity, is faced with a weakness from a scientific

Table III. Regression Results Comparing Effect of VR Versus SOC on Patient Pain and Anxiety Outcomes

Measure	Patient-report <i>M (SD)</i>			Caregiver-report <i>M (SD)</i>		
	<i>b (SE)</i>	β	<i>p</i> -value	<i>b (SE)</i>	β	<i>p</i> -value
Pain VAS						
Pain VAS Pre-Condition	.31 (.09)	0.29	.001	0.58 (0.13)	0.42	<.001
	-.62 (.32)	-.016	.053	-1.09 (0.41)	-.024	<.01
Pain Color Analogue Scale						
Pain CAS Pre-Condition	.48 (.07)	0.54	<.001	0.42 (0.09)	0.42	<.001
	-.50 (.30)	-.012	.095	-1.05 (0.36)	-.026	<.01
Faces Pain Scale—Revised						
Faces Pre-Condition	.45 (.07)	0.47	<.001	0.53 (0.11)	0.42	<.001
	-.29 (.14)	-.015	<.05	-.38 (0.21)	-.017	.07
Anxiety VAS						
Anxiety VAS Pre-Condition	.50 (.06)	0.59	<.001	0.46 (0.07)	0.53	<.001
	-.82 (.30)	-.019	<.01	-1.23 (0.40)	-.026	<.01
FAS						
FAS Pre-Condition	.57 (.07)	0.55	<.001	0.50 (0.08)	0.54	<.001
	-.13 (.03)	-.027	<.001	-.09 (0.04)	-.019	<.05

Note. Condition (SOC = 0, VR = 1); significant results are bolded. CAS = Colored Analogue Scale; FAS = Facial Affective Scale; VAS = Visual Analogue Scale.

**Figure 2.** Interaction between patient-report anxiety sensitivity and condition predicting postprocedural anxiety.

standpoint. Most VR innovators are offering the gaming consoles and platforms as frontline interventions for children and adults without conducting any pilot studies or clinical trials to evaluate the feasibility, efficacy, or effectiveness. Although the current findings may generalize to other patients undergoing blood draw, more conservatively, these results apply to children engaging in Bear Blast (appliedVR™) using the mobile-based Samsung Gear VR or Google Merge VR goggles. Other limitations include the nature of self-, caregiver-, and phlebotomist-reported outcomes as well as the lack of blinding of study personnel during postprocedure measures. Future studies may benefit from the inclusion of physiological, biological, and other objective outcome measures. In addition,

participants reported generally low pain levels during the blood draw procedure. Future research with larger sample sizes could explore additional variables that may moderate the effectiveness of VR for the prevention and amelioration of pain and anxiety during similar or more painful medical procedures. Further, generalizability of findings may be limited, given the 36% of potential participants who declined participation (most often because of time constraints), which could suggest selection bias, as those who chose to participate may have different characteristics compared with those who declined. Finally, it is important to consider why there were no significant differences by condition in procedural pain, anxiety, or cooperation according to phlebotomist-report. While phlebotomists' reported high satisfaction with the VR intervention, they also reported that the patients did well during SOC. From a social desirability standpoint, phlebotomists may wish to appear competent in their job performance or they may be less able to report on the subjective experience of their patients.

Investigating the efficacy of the new VR technologies (circa 2016) and software for a variety of medical procedures and preventive care in pediatric patients has far-reaching implications for the use of VR within medical centers and clinic settings. VR for managing procedural pain and distress may be a natural complement to SOC while improving the patient experience. Specific strengths associated with VR as a medical intervention are that it has low costs (the cost of a smartphone plus a VR head mount ranging from \$13 to \$500), is easily accessible and available to patients and families with smartphones, and young patients are becoming increasingly comfortable with new

technologies. Potential challenges for the utility of VR in a hospital setting include hospital buy-in and staff availability to manage the technology, and, most critically, the need to maintain exemplary hygiene practices to minimize/eliminate infection associated with patients sharing the technology. Though it should only take moments to set up VR games for patients in need, the additional time needed to maintain appropriate hygiene could add extra demand in the midst of a busy hospital unit. Evidence-based support for nonpharmacological interventions, such as VR, may lead to improved procedural pain management, decreased need for pharmacological interventions with known adverse side effects (e.g., narcotics; sedatives; anxiolytics; Sharar et al., 2007), increased procedural cooperation, higher caregiver and health-care provider satisfaction, and improved health outcomes for patients. Ultimately, the aim of future contemporary VR investigations should continue to develop flexible VR environments targeting specific acute and chronic pain conditions, and to promote long-term rehabilitative pain management. As new VR technology becomes more readily available, affordable, and socially acceptable, it may be a natural complement to SOC for managing procedural pain and distress while improving the patient experience. The advancement of VR in addition to SOC for pediatric pain management surrounding routine painful medical procedures, particularly for highly anxious patients, could potentially ameliorate the pain and distress experienced in pediatric medical settings, while preventing fear that may interfere with future routine procedures and medical care. While VR may have preventive care implications, many new technology and virtual environments are yet to be examined. The future of VR is now, intoning great promise and wide application. However, it is our scientific responsibility to investigate its applications and determine the best match for VR in managing acute procedural pain management and other health-related conditions.

Acknowledgments

The authors would like to acknowledge appliedVR™ for their support of the trial; the research staff Adriana Cabrales, Raquel Engilman Sloane Fisher, Melody Hannani, Arianna Lane, Ezie Nguyen, and Reina Factor; the staff and leadership in the Children's Hospital Los Angeles, Department of Pathology; and the participating children and their families.

Funding

This work was supported by applied VR™ for the purposes of staff and technology support.

Conflict of Interest: Jeffrey I. Gold, PhD serves as a scientific advisor for applied VR™.

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