

Introduction

- Researchers have long debated the accuracy and reliability of child/self-versus proxy- subjective reporting of pain.



- Previous studies have established the validity of self-report (child) and proxy-report (caregiver and healthcare provider) to reinforce the contextual circumstances of a child's treatment (von Baeyer, 2006; Varni et al., 2007).

- To date, no study has explored the advantages and disadvantages of single- versus multi-report methodology in pediatric pain management and anxiety within a virtual reality (VR) intervention.

- This study aims to investigate differences between child-, caregiver-, and healthcare provider- (HCP) ratings of pain and anxiety in a randomized controlled trial of VR.

Methods

One hundred and seven patients (boys = 59%; age range = 10-21) undergoing IV placement in the infusion or outpatient radiology centers were recruited from an urban, academic pediatric hospital.

Participants were randomized to one of two conditions for their IV start:

1. **Standard of care (SOC)**
2. **SOC plus VR:** Patients played BearBlast (appliedVR™) on the Samsung Gear VR goggles (ages 13-21) or the Google Merge VR goggles (ages 10-12)

Patients and their caregivers completed standardized self-report measures of pain and anxiety before and after the IV start procedure. HCPs reported child peri-procedural pain and anxiety.

- Pain was measured using the Faces Pain Scale-Revised (Hicks et al., 2001) which includes six faces ranging from “no pain” to “very much pain.”
- Anxiety was measured using a Visual Analogue Scale ranging from 0-10 (no anxiety to most anxiety).
- Anxiety sensitivity was measured using the Childhood Anxiety Sensitivity Index (CASI; Silverman et al., 1991), an 18-item, 3-point Likert scale.

Statistical Plan: Generalized linear mixed modeling was used to control for the correlation of the three ratings performed on the same child. Backwards, stepwise selection was used to determine factors associated with the outcome based on statistical significance and the influence on a parameter estimate changing by +/- 20%. The effect of who was rating was assessed at the 0.05 significance level. The blocking factors gender and location, as well as the pre-score and main variable of interest ‘rater,’ were all kept in the model regardless of significance.

Results

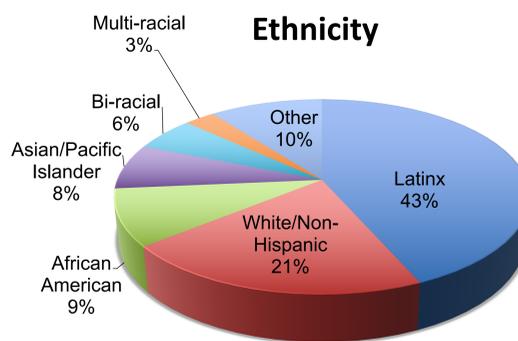


Table 1. Demographics*

Age	Years
Median (Q1, Q3)	14.7 (12.8, 16.9)
Gender	n (%)
Girls	44 (41.1%)
Boys	63 (58.9%)
Location	n (%)
Radiology	42 (39.3%)
Infusion Center	65 (60.7%)
Caregiver type**	n (%)
Mothers	64 (73.57%)
Fathers	18 (20.69%)
Other legal guardians	5 (5.75%)

*There were no significant differences in demographics between the VR and SOC groups.
 **15 out of 107 patients were ages 18+ years old. Caregiver data was not collected from 18+ patients.

Table 2. Observed Median Outcome Scores with Interquartile Range

	Child	Caregiver	HCP
Post-Pain Score (n, IQR)	2.00 (107, 2.00)	2.00 (89, 4.00)	2.00 (103, 2.00)
Post-Anxiety score (n, IQR)	1.75 (106, 3.28)	1.80 (86, 4.53)	2.00 (103, 4.00)

Table 3. Generalized Linear Mixed Modeling Results

	Outcome: Post-Pain		Outcome: Post-Anxiety	
	Estimate (95% CI)	p-value	Estimate (95% CI)	p-value
VR vs. SOC	-1.33 (-1.93, -0.74)	<0.0001	-1.18 (-1.80, -0.55)	0.0003
Caregiver vs. Child	0.48 (0.05, 0.91)	0.03	0.21 (-0.39, 0.81)	0.49
HCP vs. Child	0.84 (0.37, 1.30)	0.0005	0.16 (-0.33, 0.65)	0.51
Age	-0.13 (-0.23, -0.03)	0.01	-0.10 (-0.21, 0.02)	0.10
Gender 0 vs. 1	0.03 (-0.58, 0.64)	0.93	0.41 (-0.24, 1.05)	0.21
Location 1 vs. 2	-0.27 (-0.79, 0.26)	0.32	-0.21 (-0.83, 0.40)	0.50
Child CASI Sum	0.06 (0.01, 0.12)	0.02	-	-
Child Pre-Score	0.25 (0.09, 0.42)	0.0027	0.45 (0.26, 0.64)	<0.0001

Conclusions

- Measuring pain and anxiety in pediatrics continues to pose significant challenges as investigators are reliant on subjective self-reports.
- Data reflected that raters differed in their child pain reports, but not their child anxiety reports.
- Caregivers and HCPs rated child pain as significantly higher than that of child self-report.
- The current study indicates that the triangulation of multi-reporters may be critical for pediatric trials. Future studies will benefit from multi-reporter models and the incorporation of objective data (e.g. biometrics).

