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Effectiveness of Artificial Intelligence-Assisted Virtual Reality Distraction on Procedural Pain and Distress in Preschool Children Undergoing Invasive Procedures: A Simulation Study

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ABSTRACT

Background & Aim: Needle-related procedures cause pain and distress in preschool children, and conventional virtual reality distraction cannot adapt to a child's changing state. This study aimed to evaluate an artificial intelligence-assisted adaptive virtual reality distraction tool for reducing procedural pain and behavioral distress in preschool children undergoing invasive procedures.

Methods & Materials: This simulation study used a two-arm randomized framework with synthetic profiles of 120 children aged 3-6 years undergoing venipuncture, intravenous cannulation, intramuscular injection or blood sampling. The study was carried out in the Sv hospital, Sangareddy, Sangareddy (Dist), Telangana, India. Profiles were allocated by block randomization to adaptive virtual reality distraction (n = 60) or customary care with simple verbal distraction (n = 60). Pain was assessed with the Face, Legs, Activity, Cry and Consolability scale and behavioral distress with the Observational Scale of Behavioral Distress-Revised. The present study were ethically approved. Secondary outcomes were heart rate, procedure duration, first-attempt success, cooperation and caregiver satisfaction. Random forest, logistic regression and support vector machine classifiers were compared for distress classification.

Results: The intervention group had lower procedural pain (mean 3.21 versus 4.16) and behavioral distress (2.87 versus 5.52) than the control group (both $p < 0.001$). Heart rate during the procedure was lower, procedures were shorter, and cooperation and caregiver satisfaction were higher with the intervention. First-attempt success was higher after adjustment (adjusted odds ratio 3.18). Classifier accuracy ranged from 80.0% to 88.3%.

Conclusion: In this simulation, adaptive virtual reality distraction was associated with lower procedural pain and distress in preschool children. These hypothesis-generating findings require confirmation in a registered clinical trial with real participants.

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1. Introduction

Needle-related procedures are distressing for children and may lead to behavioral problems and heightened arousal (1). Young children are particularly prone to distress and non-cooperation because they have limited understanding of why a procedure is needed and depend on caregivers for support. Repeated unpleasant experiences may lead to fear of healthcare settings, and recent pediatric nursing practice has therefore emphasized distraction as an alternative to physical restraint (1,2).

Distraction with a variety of stimuli, including virtual reality (VR), has reduced procedure-related anxiety, fear and discomfort (3-7), although reductions in procedural pain have been less consistent. Several studies have found that simpler forms of distraction, such as an audio-video player, may be as effective as more complex VR distraction in some situations (8-12).

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A limitation of current VR applications is that the level of interactivity and the complexity of tasks are usually fixed (13). In game design, user or player models allow characters and interactions to vary with the player's skills and behavior (14-15). In a clinical setting, behavioral and physiological signals could similarly indicate a child's level of distress, anxiety or engagement and prompt adjustments to the VR experience; for example, one child may want to play a game with a VR character while another prefers to avoid interaction(16-17). User models and machine-learning techniques could therefore tailor the level of distraction and engagement to each child's needs, helping to control anxiety and improve procedure tolerance (18-19).

This study aimed to evaluate, within a simulated randomized framework, the effectiveness of an artificial intelligence (AI)-assisted adaptive VR distraction tool (AI-VR) on procedural pain and behavioral distress among preschool children undergoing invasive procedures. Compared with customary care, AI-VR was hypothesized to (1) reduce pain scores, (2) reduce observer-rated procedural distress, (3) attenuate the rise in heart rate during the procedure, and (4) increase cooperation and first-attempt procedural success.

2. Methods

Study design

This was a simulation study using a two-arm, parallel-group randomized framework, reported with reference to the Consolidated Standards of Reporting Trials (CONSORT) statement (20). All participant data were generated synthetically to model children undergoing invasive procedures; no children were enrolled. The present study was carried out in the Sv hospital, Sangareddy, Sangareddy (Dist), Telangana, India.

Participants and sample size

The simulated sample comprised 120 children aged 3-6 years undergoing venipuncture, intravenous cannulation, intramuscular injection or blood sampling. Profiles modeled children able to wear a head-mounted display (HMD) and interact with VR. Children with major neurological or cognitive disability, unstable cardiorespiratory conditions, nausea or vertigo were excluded from the modeled population.

The required sample was estimated at 52.87 children per group to detect a moderate effect size with 80% power, using $n = 2(Z\alpha/2 + Z\beta)^2/d^2$. Allowing for 10% attrition, 65 children per group were planned, and the simulation used 120 children (60 per group).

Randomization and allocation

Profiles were allocated 1:1 to the two groups by block randomization with block sizes of 4 and 6. Allocation was concealed with sequentially numbered opaque assignments. Because the intervention is visible, children and bedside nurses could not be blinded; behavioral scoring and data analysis were modeled as being performed by blinded personnel.

Intervention

The AI-VR program started 5 minutes before the procedure and continued throughout needle insertion or injection and for 2 minutes afterwards (3). Children engaged with interactive games set in virtual environments such as an ocean or a forest, with prompts to direct gaze and head movement, paced breathing, narration and visual feedback (12). Interaction demands were kept low so that the child could maintain the position required by the clinician (21). Headset surfaces were disinfected and facial interfaces were replaced between users (22-23).

Control condition

The control group received the customary child- and parent-directed support and preparation provided by staff, with simple non-VR distraction such as verbal distraction, representing usual pediatric care (12).

Artificial intelligence module

The AI module provided decision support. Input features were age, baseline distress and heart rate, recent change in heart rate, head and gaze movement, interaction frequency and latency, and the child's response to the previous interaction. Distress level (low, moderate or high) was predicted with a random forest classifier, whose performance was compared with logistic regression and support vector machine (SVM) models using accuracy, macro-averaged sensitivity and specificity, precision, recall, F1-score and the one-versus-rest macro-averaged area under the receiver operating characteristic curve (ROC-AUC) (21,22). Predictions guided the choice of distraction content and the timing of paced-breathing prompts. The random forest model was configured to run on an edge or mobile

device, with the most demanding cases handled by encrypted, isolated virtual machines. The module could change only the distraction content, and a caregiver could switch it off at any time.

Measurements

Procedural pain was rated with the Face, Legs, Activity, Cry and Consolability (FLACC) scale, which scores five items from 0 to 2 for a total of 0-10 and has adequate reliability and validity in children (24). Behavioral distress was rated with the Observational Scale of Behavioral Distress-Revised (OSBD-R), which has good inter-rater reliability and validity in children aged 2-12 years (2). The Observational Scale of Behavioral Distress–Revised (OSBD-R) has a commonly reported score range of 0–23.5, where 0 indicates no observed distress and 23.5 indicates maximum distress under the scoring protocol. Some studies report maximum values of 21.5 or 22, depending on the scoring description or protocol used. **OSBD-R scoring range**

Score	Interpretation
0	No observed behavioral distress
0–23.5	Full reported scoring range
Higher score	Greater observed behavioral distress

Heart rate and oxygen saturation were recorded at baseline (T0), immediately before the procedure (T1), during the procedure (T2) and immediately after it (T3). Other outcomes were transient adverse effects and tolerance of VR, child cooperation (scored 1-5), procedure duration, number of attempts, first-attempt success and caregiver satisfaction (scored 1-5).

Data analysis

All analyses were two-sided with alpha set at 0.05. Continuous variables are presented as means with standard deviations, and as medians with interquartile ranges (IQR) where applicable; categorical variables are presented as frequencies and percentages. Normality and equality of variances were assessed with the Shapiro-Wilk and Levene's tests. Baseline differences were assessed with independent-samples t tests and chi-square tests. Continuous outcomes were compared with independent-samples t tests with 95% confidence intervals (CI), and categorical outcomes with chi-square or Fisher's exact tests. No, universally validated cut-off values have been established to classify OSBD-R scores into mild, moderate, or severe distress; therefore, such classifications should only be applied when supported by validated, study-specific criteria. Random-intercept mixed models assessed the effects of time, group and their interaction over the measurement points. FLACC and distress scores were analyzed with multiple linear regression adjusted for age, sex, baseline distress, previous procedure experience and procedure type, and first-attempt success with logistic regression. AI metrics are based on five-fold out-of-fold predictions.

Ethical Considerations

Because all participant data were generated synthetically, no children or caregivers were enrolled, and ethics committee approval, parental consent and child assent were not required. The approval of ethical clearance reference DHR-NECRBHR: File No. EC/NEW/INSTI2025/5370 IEC-Reference Number: 003/05/2026/1EC/SMCH, dated on 11-05-2026. The AI component was designed according to principles of responsible, human-centered pediatric AI, including explainability, fairness and data minimization (23,25,26).

3. Results

Baseline characteristics

The dataset comprised 120 simulated children, 60 per group, with a mean age of 4.48 years in both groups. The groups did not differ in sex, procedure type, previous procedure experience, baseline heart rate or baseline distress (all $p > 0.05$; Table 1).

Procedural pain and behavioral distress

Procedural pain and behavioral distress were lower in the AI-VR group than in the control group (both $p < 0.001$; Table 2). Median FLACC scores were 3.12 (IQR 2.44-4.02) and 4.31 (IQR 3.53-4.71), and median distress scores were 2.99 (IQR 2.00-3.80) and 5.62 (IQR 4.80-6.35), respectively. Both differences remained significant after adjustment for age, sex, baseline distress, previous procedure

experience and procedure type. Behavioral distress was lower in the AI-VR group immediately before, during and after the procedure (Table 3).

Physiological and procedural outcomes

During the procedure, heart rate was 5.88 bpm lower in the AI-VR group (95% CI -8.39 to -3.36; $p < 0.001$; $d = -0.85$), with a significant time-by-group interaction ($p < 0.001$; Table 3). Oxygen saturation did not differ between groups. Procedures were shorter, and cooperation and caregiver satisfaction were higher, in the AI-VR group (all $p < 0.001$; Table 2). First-attempt success was 86.7% versus 71.7% (Fisher's exact $p = 0.071$); after adjustment, the odds of first-attempt success were higher with AI-VR (adjusted odds ratio [OR] 3.18, 95% CI 1.16-8.69; $p = 0.024$).

Artificial intelligence performance, safety and acceptability

Random forest achieved 80.0% accuracy and a ROC-AUC of 0.926; logistic regression and SVM performed slightly better (Table 4). Random forest was retained for implementation because its shallow ensemble allows feature inspection and on-device inference, although external validation is required. Of the 60 AI-VR profiles, 55 (91.7%) tolerated the headset, 3 (5.0%) had mild transient dizziness and 2 (3.3%) had headset-related discomfort; no serious adverse events occurred.

4. Discussion

In this simulation, AI-assisted VR distraction was associated with lower procedural pain and behavioral distress, a smaller heart-rate response, shorter procedures, better cooperation and higher caregiver satisfaction than customary care. Oxygen saturation did not differ, and the unadjusted difference in first-attempt success was not statistically significant, although it became significant after adjustment. In clinical settings, greater variation in children's perceptions of pain and anxiety would be expected because of external factors.

These findings are consistent with trials of VR during venipuncture and other painful procedures (1,3), although one randomized trial found VR no better than simple distraction during pediatric orthopedic procedures (12). A distinctive feature of the present tool is that it adapts distraction content to the child's estimated distress, an approach that has rarely been tested.

Several factors will determine the clinical relevance of AI-VR, including its expected impact, disruption to workflow, cost, usability, staff acceptance and dependence on technology. Used alongside other strategies, VR may help prepare and distract children during procedures. Large, well-designed studies should evaluate the cost per procedure, validate distress classification in real patients and obtain external review of the classification model (16,21-23).

Implementation framework for AI-assisted VR in pediatric practice

AI-enabled VR has emerged as a potential strategy for minimizing pain, anxiety and emotional distress in children undergoing invasive procedures (27). Nevertheless, evidence on its effectiveness, feasibility and integration into routine pediatric nursing practice is limited. Previous research has focused mainly on VR as a fixed distraction technique, while AI-based personalization and real-time adaptation remain largely unexplored. Preschool children are also under-investigated, despite their greater susceptibility to procedural discomfort and psychological distress Evidence is also limited on standardized clinical protocols, staff training, implementation costs, parental perceptions and long-term outcomes.

A practical implementation process is proposed. First, the nurse assesses time sensitivity, contraindications, infection control and the child's tolerance of the headset. Second, the nurse assesses the child's communication, behavior and developmental level (28). Third, the child's emotional state and distress are assessed, optionally with heart rate. Fourth, the headset is prepared, and fifth, general, non-identifying information is entered immediately before the session. The session lasts at least 5 minutes and may include breathing exercises, with nursing staff supervising and interacting with the child as needed (27). Staff should document the session, including adverse effects, distress and procedure tolerance; sensor data should be deleted unless storage is required; and staff should be trained to manage device problems so that device failure never delays the child's procedure or care.

Nursing implications

Given its potential benefits, VR is likely to become more widely available to pediatric nurses (16). Once deployed, its main role will be responsive distraction that allows staff to perform procedures with less distress for the child (21). Before routine use, nurses and managers will need to assess usability, equipment maintenance and costs (27).

Limitations

This study has several limitations. Most importantly, all data were simulated, so the results do not show what would happen with real children in hospital, and they depend on simplifying assumptions, including full staff adherence to the protocol. A simulation cannot capture the full complexity of clinical practice, long-term effects could not be evaluated, and the AI model was developed for an assumed patient population and may not generalize to other populations.

5. Conclusion

In this simulation study, AI-assisted VR distraction was associated with lower procedural pain, behavioral distress and heart-rate response in preschool children, together with better cooperation and caregiver satisfaction. Its ability to adapt to each child's engagement and response is a potential advantage over fixed-content VR. Because these results come from simulated data, large randomized clinical trials with real children are needed to confirm effectiveness, and such trials should include caregiver engagement and perspectives.

Relevance to clinical practice

Adaptive VR distraction could give pediatric nurses a non-pharmacological tool for reducing pain and distress during needle procedures, but it should not be adopted routinely until its effectiveness, safety and costs are confirmed in clinical trials.

Author Contributions (CRediT)

Sunilkumari Puram: Investigation, Data curation, Formal analysis, Writing – original draft.
Dr. Subbarayalu Alagendran: Conceptualization, Methodology, Validation, Visualization, Writing – review & editing, Supervision.
Dr. T. K. Sreedevi: Conceptualization, Resources, Project administration, Writing – review & editing.

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Conflict of interest

The authors declare that they have no conflict of interest.

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Table 1. Demographic and clinical characteristics of participants (n = 120)

Characteristic	AI-VR (n = 60)	Control (n = 60)	P value
Age, years	4.48 ± 1.03	4.48 ± 0.97	1.000
Baseline heart rate, bpm	97.49 ± 5.05	95.87 ± 5.94	0.110
Baseline distress score	1.17 ± 0.83	1.28 ± 0.68	0.405
Sex, boy / girl	27 (45.0) / 33 (55.0)	32 (53.3) / 28 (46.7)	0.465
Previous invasive procedure, yes	29 (48.3)	31 (51.7)	0.855
Procedure type			0.432
Venipuncture	21 (35.0)	25 (41.7)	-
Intravenous cannulation	19 (31.7)	16 (26.7)	-
Intramuscular injection	15 (25.0)	10 (16.7)	-
Blood sampling	5 (8.3)	9 (15.0)	-

Values are mean ± SD or n (%). P values from independent-samples t tests or chi-square tests. AI-VR, artificial intelligence-assisted virtual reality; bpm, beats per minute.

Table 2. Primary and secondary outcomes by group

Outcome	AI-VR (n = 60)	Control (n = 60)	Difference (95% CI)	Adjusted estimate (95% CI)[a]	P value
FLACC procedural pain (0-10)	3.21 ± 1.02	4.16 ± 0.92	-0.94 (-1.29 to -0.59)	β -0.96 (-1.31 to -0.61)	< 0.001
Behavioral distress	2.87 ± 1.19	5.52 ± 1.16	-2.66 (-3.08 to -2.23)	β -2.60 (-3.01 to -2.19)	< 0.001
Heart rate at T2, bpm	107.18 ± 6.71	113.06 ± 7.19	-5.88 (-8.39 to -3.36)	-	< 0.001
Oxygen saturation at T2, %	98.12 ± 0.60	98.00 ± 0.69	0.12 (-0.11 to 0.35)	-	0.305
Procedure duration, min	4.16 ± 0.81	5.24 ± 0.73	-1.08 (-1.36 to -0.80)	-	< 0.001
Cooperation (1-5)	3.87 ± 0.72	2.48 ± 0.81	1.38 (1.11 to 1.66)	-	< 0.001
Caregiver satisfaction (1-5)	4.30 ± 0.56	3.33 ± 0.54	0.97 (0.77 to 1.17)	-	< 0.001

Outcome	AI-VR (n = 60)	Control (n = 60)	Difference (95% CI)	Adjusted estimate (95% CI)[a]	P value
First-attempt success, n (%)	52 (86.7)	43 (71.7)	OR 2.57	OR 3.18 (1.16 to 8.69)	0.071[b] / 0.024[c]
Attempts 1 / 2 / 3, n	52 / 8 / 0	43 / 15 / 2	Cramer's V 0.204	-	0.083

Values are mean ± SD unless stated. [a] Adjusted for age, sex, baseline distress, previous invasive-procedure experience and procedure type; β, unstandardized regression coefficient. [b] Fisher's exact test. [c] Adjusted logistic regression. AI-VR, artificial intelligence-assisted virtual reality; CI, confidence interval; FLACC, Face, Legs, Activity, Cry and Consolability scale; OR, odds ratio; T2, during the procedure.

Table 3. Heart rate and behavioral distress from baseline to after the procedure

Measure and time point	AI-VR, mean ± SD	Control, mean ± SD	Between-group P	Time × group P
Heart rate, bpm: T0	97.49 ± 5.05	95.87 ± 5.94	0.110	< 0.001
Heart rate, bpm: T1	99.94 ± 5.48	99.39 ± 6.84	0.628	-
Heart rate, bpm: T2	107.18 ± 6.71	113.06 ± 7.19	< 0.001	-
Heart rate, bpm: T3	100.48 ± 5.67	101.65 ± 6.26	0.286	-
Behavioral distress: T0	1.17 ± 0.83	1.28 ± 0.68	0.405	< 0.001
Behavioral distress: T1	1.43 ± 0.98	2.24 ± 0.77	< 0.001	-
Behavioral distress: T2	2.87 ± 1.19	5.52 ± 1.16	< 0.001	-
Behavioral distress: T3	1.54 ± 0.71	2.20 ± 0.70	< 0.001	-

T0, baseline; T1, immediately before the procedure; T2, during the procedure; T3, immediately after the procedure. Time × group P is the omnibus mixed-model interaction test for each outcome. AI-VR, artificial intelligence-assisted virtual reality; bpm, beats per minute.

Table 4. Cross-validated performance of distress-classification models

Model	Accuracy	Sensitivity	Specificity	Precision	F1-score	ROC-AUC
Random forest	0.800	0.800	0.900	0.808	0.785	0.926
Logistic regression	0.817	0.817	0.908	0.814	0.815	0.936
Support vector machine	0.883	0.883	0.942	0.901	0.886	0.949

Macro-averaged metrics from five-fold out-of-fold predictions in the simulated AI-VR group; recall equals sensitivity. These are technical, not diagnostic, performance estimates. ROC-AUC, area under the receiver operating characteristic curve.