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Virtual reality distraction for procedural pain and anxiety in children undergoing intravenous cannulation: A comparative study

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Abstract:
Needle-related procedures are a common source of avoidable pain and anxiety in children and virtual reality (VR) offers immersive, non-pharmacological distraction. Therefore, it is of interest to evaluate the VR distraction versus routine care in 126 children aged 5-15 years undergoing peripheral intravenous cannulation (63 per group), assessing pain on the Faces Pain Scale-Revised and anxiety on the Visual Facial Anxiety Scale. Post-procedure pain was significantly lower with VR (3.24 ± 2.79 vs 4.84 ± 2.70; P = 0.001) and the reduction in anxiety was substantially greater (1.94 ± 1.37 vs 0.43 ± 0.61; P < 0.001). Complete absence of pain (23.8% vs 1.6%) and complete resolution of anxiety (41.3% vs 6.3%) were more frequent with VR, benefits persisted after adjustment and greater engagement predicted lower pain and greater anxiety relief. Thus, VR distraction is an effective, safe and practical adjunct for reducing procedural pain and anxiety in children, including in resource-constrained settings.

Keywords: Virtual reality (VR), procedural pain, anxiety, children, intravenous cannulation, distraction, paediatric surgery

Background:
Peripheral intravenous cannulation is among the commonest procedures performed on hospitalised children and among the most distressing and fear of needles affects an estimated two-thirds of children **[1].** Unmanaged procedural pain is neither trivial nor transient and can seed lasting needle phobia, healthcare avoidance and medical traumatic stress that persist into adult life **[2].** Non-pharmacological distraction using conversation, toys, television or caregiver presence is inexpensive and widely used, but its effect depends heavily on the skill and availability of the person delivering it **[3].** According to gate control theory, distraction that consumes finite attentional capacity leaves fewer resources available to process nociceptive input **[4].** Virtual reality (VR) extends this principle by occupying vision, hearing and motor attention simultaneously and functional imaging shows attenuated activity in pain-processing regions during immersive distraction **[5].** Meta-analytic evidence indicates that VR reduces pain and anxiety during needle-related procedures in the paediatric emergency department **[6].** A meta-analysis of children undergoing vein puncture similarly reported significant reductions in both pain and anxiety with VR **[7].** A systematic review with meta-analysis across needle-related procedures in childhood and adolescence reached the same qualitative conclusion **[8].** Reliable evaluation of these outcomes requires validated self-report instruments, such as the Faces Pain Scale-Revised for procedural pain **[9]** and the Visual Facial Anxiety Scale for procedural anxiety **[10].** Therefore, it is of interest to evaluate the virtual reality distraction against routine care for procedural pain and anxiety and to assess its feasibility, acceptability and safety, in children aged 5-15 years undergoing intravenous cannulation in a tertiary Indian paediatric surgical service.

Materials and Methods:

Study design and setting:
This prospective, comparative study was conducted in the Departments of Paediatric Surgery, Paediatric Medicine and Emergency at a tertiary care teaching hospital in central India. The protocol was approved by the Institutional Human Ethics Committee (Approval number: IHEC-LOP/2025/IP084; 12 April 2025) and the study was conducted in accordance with the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and the Declaration of Helsinki. Written informed consent was obtained from a parent or legal guardian, with assent from children old enough to provide it.

Participants and sample size:
Children aged 5-15 years requiring peripheral intravenous cannulation were eligible. Children with a history of epilepsy, those with developmental delay and those unable to communicate adequately for self-report pain assessment were excluded. The sample size was calculated for the comparison of two independent means, assuming a standard deviation of 2 points on the outcome scales, a clinically meaningful between-group difference of 1 point, 80% power and a two-sided significance level of 5%; this yielded 63 children per group and a total of 126.

Grouping and intervention:
After written informed consent was obtained, consecutive eligible children were allocated on an alternate basis, the first child to VR distraction using a head-mounted display and the next to routine care, yielding 63 participants per group. Children allocated to VR received distraction through a commercially available head-mounted display (Meta Quest 3). Each child was primed with VR content for three to five minutes before the procedure and could change the content if the initial selection was not to their liking. Content was chosen by age: gentle exploratory and job-simulation environments for children aged

5-8 years, an interactive game for those aged 9-12 years and a three-dimensional drawing application suitable for all ages. Content began at least one minute before the procedure and continued for at least two minutes afterwards, giving a total exposure of five to seven minutes. Children in the control group received routine care, comprising conventional verbal reassurance and diversion by parents, caregivers and ward staff.

Outcomes and measurements:

The primary outcomes were procedural pain, self-reported on the Faces Pain Scale-Revised (FPS-R, 0-10) and procedural anxiety, self-reported on the Visual Facial Anxiety Scale (VFAS, 0-6), both recorded immediately before and immediately after the procedure. Secondary outcomes were feasibility (ability to understand and cooperate with the headset), acceptability (response to initial VR exposure, rated 0 = did not like it to 5 = very interesting) and safety (any complication, including fright, nausea, vomiting or refusal).

Statistical analysis:

As the pre-procedure FPS-R score was zero in all 126 participants, pain was analysed as the post-procedure score compared between groups, whereas anxiety, which varied at baseline, was analysed both as a within-group change and as a between-group difference in reduction. Continuous variables are summarised as mean ± standard deviation and median (interquartile range) and categorical variables as counts and percentages. Between-group comparisons used the Mann-Whitney U test, within-group comparisons the Wilcoxon signed-rank test and categorical comparisons the Pearson chi-square or Fisher's exact test. Effect sizes are reported as Cohen's d and as r, with 95% confidence intervals for mean differences obtained by bootstrap resampling (5000 iterations). Multivariable linear regression estimated the effect of allocation on post-procedure pain and on anxiety reduction after adjustment for baseline anxiety, age and sex and logistic regression modelled the odds of achieving no or mild post-procedure pain. Correlations within the VR group were assessed by Spearman's rank coefficient. A two-sided P value below 0.05 was considered significant.

Results:

Of 152 children assessed for eligibility, 26 were excluded (11 developmental delay, 6 epilepsy 5 unable to self-report pain 4declined consent). The remaining 126 were divided equally between the two groups; all received their allocated intervention, completed assessments and were analysed, with no crossover or loss to follow-up. The groups were comparable for age and sex although baseline anxiety was modestly higher in the VR group (**Table 1)**.VR was feasible in 62 of 63 children (98.4%). The mean response to initial exposure was 3.41 ± 1.23 on the 0-5 scale (median 4.0, IQR 3.0-4.0) and 50 children (79.4%) rated their experience favourably (score ≥ 3). One child (1.6%) refused to wear the headset, which constituted the only adverse event and the only failure of cooperation. No child reported nausea, vomiting or fright and no procedure-related complication was recorded in either group. Children in the VR group reported significantly less pain during the procedure than those receiving routine care, with a medium-to-large effect. Anxiety fell significantly from before to after the procedure in both groups, but the magnitude of the fall differed markedly: the VR group achieved a reduction approximately four and a half times larger than controls and ended the procedure with lower residual anxiety despite a higher starting score (**Table 2, Figure 1).** The post-procedure distribution of pain severity and of anxiety categories differed significantly between groups, with VR shifting children away from the severe bands towards no or mild symptoms **(Table 3).** Complete absence of pain and complete resolution of anxiety were both markedly more frequent with VR. Predefined thresholds for a clinically meaningful response were met by significantly more VR children on every criterion, with the widest separation at the more demanding thresholds **(Table 4).** The anxiety benefit was consistent and significant across every age and sex stratum **(Figure 2).** The pain benefit was directionally consistent throughout but reached significance in younger children and in girls only given the unequal stratum sizes these comparisons are exploratory. Within the VR group, children who engaged more with the virtual environment reported lower pain and achieved greater anxiety reduction **(Figure 3)** and children with higher baseline anxiety achieved larger reductions (ρ = 0.33, P = 0.009). After adjustment for baseline score, age and sex, the estimated effect of VR on both outcomes was essentially unchanged from the unadjusted comparison, indicating that the benefit was not an artefact of the baseline anxiety imbalance **(Table 5).** Independent of allocation, older children reported less procedural pain and children with higher baseline anxiety achieved greater anxiety reduction; sex was not associated with either outcome. Proportions achieving complete absence of pain and complete resolution of anxiety are given in **Table 3.**

Table 1: Baseline demographic and clinical characteristics of the study groups

Characteristic	VR group (n = 63)	Control group (n = 63)	P value
Age, years — mean ± SD	9.09 ± 3.12	9.32 ± 3.19	0.686[a]
Age 5-9 years, n (%)	34 (54.0)	33 (52.4)	0.923[c]
Age 10-15 years, n (%)	28 (44.4)	30 (47.6)	
Male, n (%)	50 (79.4)	48 (76.2)	0.830[c]
Female, n (%)	13 (20.6)	15 (23.8)	
Baseline anxiety, VFAS (0-6) — mean ± SD	3.25 ± 1.22	2.57 ± 1.35	0.017[b]*
Baseline anxiety, VFAS — median (IQR)	3.0 (3.0-4.0)	3.0 (1.0-4.0)	—
Baseline pain, FPS-R (0-10)	0	0	—

*VFAS = Visual Facial Anxiety Scale; FPS-R = Faces Pain Scale-Revised. [a] Independent-samples t test; [b] Mann-Whitney U test; [c] Pearson chi-square test. *Significant at P < 0.05. Age was missing for one VR child, so age-band percentages for that group are based on n = 62.*

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Table 2: Procedural pain and anxiety: between-group comparison and effect sizes

Outcome	VR group (n = 63)	Control group (n = 63)	Mean difference (95% CI)
Pain, FPS-R (0-10) — post-procedure, mean ± SD	3.24 ± 2.79	4.84 ± 2.70	−1.60 (−2.52 to −0.63); P = 0.001*
Pain — post-procedure, median (IQR)	2.0 (2.0-4.0)	4.0 (2.0-7.5)	—
Pain — effect size (Cohen's d; r)	−0.58; 0.28		
Anxiety, VFAS (0-6) — before, mean ± SD	3.25 ± 1.22	2.57 ± 1.35	+0.68 (0.23 to 1.13); P = 0.017*
Anxiety — after, mean ± SD	1.32 ± 1.56	2.14 ± 1.41	−0.82 (−1.34 to −0.30); P < 0.001*
Anxiety — reduction, mean ± SD	1.94 ± 1.37	0.43 ± 0.61	+1.51 (1.13 to 1.87); P < 0.001*
Anxiety — relative reduction (%)	59.5	16.7	—
Anxiety — within-group P value	<0.001*	<0.001*	—
Anxiety — effect size (Cohen's d; r)	1.42; 0.57		

*Between-group comparisons by Mann-Whitney U test; within-group by Wilcoxon signed-rank test. *Significant at P < 0.05. Negative values for pain indicate lower pain with VR. Confidence intervals were obtained by bootstrap resampling (5000 iterations).*

Table 3: Distribution of post-procedure pain severity and of anxiety categories

Category	Pain VR	Pain Control	Anxiety before VR	Anxiety before Control	Anxiety after VR	Anxiety after Control
None	15 (23.8)	1 (1.6)	0 (0.0)	0 (0.0)	26 (41.3)	4 (6.3)
Mild	18 (28.6)	23 (36.5)	14 (22.2)	28 (44.4)	21 (33.3)	30 (47.6)
Moderate	22 (34.9)	22 (34.9)	43 (68.3)	33 (52.4)	13 (20.6)	27 (42.9)
Severe / high	8 (12.7)	17 (27.0)	6 (9.5)	2 (3.2)	3 (4.8)	2 (3.2)

Values are n (%). Pain bands: none = 0, mild = 1-3, moderate = 4-6, severe = 7-10 (FPS-R). Anxiety bands: none = 0, mild = 1-2, moderate = 3-4, high = 5-6 (VFAS). Post-procedure distributions differed significantly between groups for pain (chi-square P = 0.001) and anxiety (P < 0.001); differences in the proportions with no pain and no residual anxiety were also significant (Fisher's exact P < 0.001 for both).

Table 4: Responder analysis — proportion of children achieving a clinically meaningful response

Domain	Response criterion	VR, n (%)	Control, n (%)	P value[a]
Pain	No or mild pain (FPS-R ≤ 2)	33/63 (52.4)	18/63 (28.6)	0.011*
Anxiety	≥ 1-point reduction	52/63 (82.5)	23/63 (36.5)	<0.001*
Anxiety	≥ 2-point reduction	40/63 (63.5)	4/63 (6.3)	<0.001*
Anxiety	≥ 50% relative reduction	46/63 (73.0)	14/63 (22.2)	<0.001*

*[a] Fisher's exact test. *Significant at P < 0.05.*

Table 5: Multivariable analysis of the adjusted effect of VR, controlling for baseline score, age and sex

Predictor	Coefficient (95% CI)	P value
Panel A — Post-procedure pain (linear regression; R^2 = 0.19)		
VR vs control (β)	−1.77 (−2.67 to −0.86)	<0.001*
Age, per year (β)	−0.27 (−0.42 to −0.13)	<0.001*
Male sex (β)	−0.32 (−1.41 to 0.77)	0.562
Panel B — Anxiety reduction (linear regression; R^2 = 0.44)		
VR vs control (β)	+1.44 (1.09 to 1.80)	<0.001*
Baseline anxiety, per point (β)	+0.21 (0.07 to 0.36)	0.005*
Age, per year (β)	+0.06 (−0.00 to 0.12)	0.052
Male sex (β)	−0.23 (−0.65 to 0.19)	0.274
Panel C — No or mild post-procedure pain, FPS-R ≤ 2 (logistic regression)		
VR vs control (OR)	3.26 (1.49 to 7.12)	0.003*
Age, per year (OR)	1.20 (1.06 to 1.37)	0.004*
Male sex (OR)	0.79 (0.32 to 1.98)	0.622

*β = adjusted regression coefficient; OR = adjusted odds ratio. *Significant at P < 0.05. Control is coded 0 and VR 1; sex effects are relative to females. Models exclude the one child with a missing age (n = 125). Baseline pain is not a covariate because it was zero in all children.*

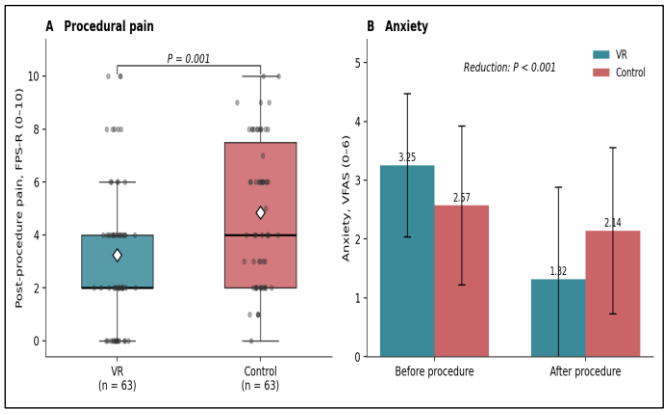


Figure 1: Primary outcomes by group. (A) Post-procedure pain (FPS-R): boxes show the median and interquartile range, diamonds the mean and points individual children. (B) Anxiety (VFAS) before and after the procedure, mean ± standard deviation

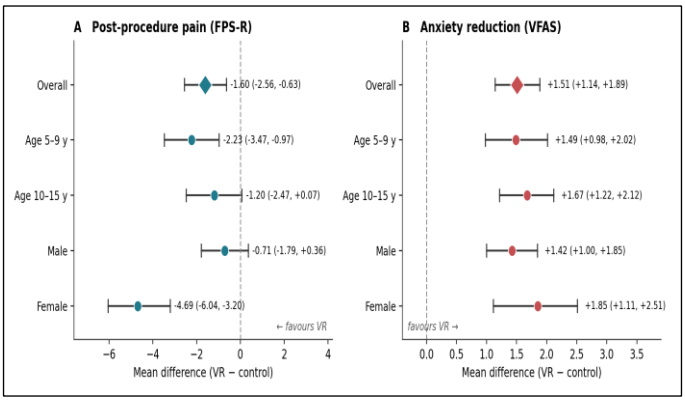


Figure 2: Subgroup analysis of the between-group difference (VR minus control) for (A) post-procedure pain and (B) anxiety reduction. Markers show the mean difference and horizontal lines the bootstrap 95% confidence interval; the dashed line marks no difference. Diamonds denote the overall estimate

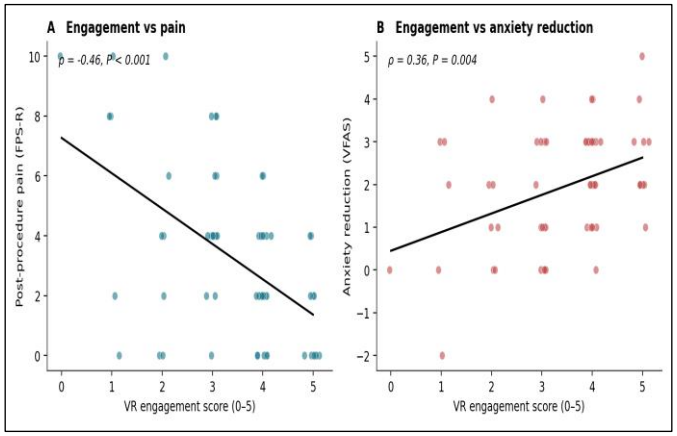


Figure 3: Dose-response within the VR group. (A) VR engagement score versus post-procedure pain. (B) VR engagement score versus anxiety reduction. Points are individual children with slight horizontal jitter; lines are least-squares fits. ρ = Spearman rank correlation coefficient

Discussion:

In this prospective comparative study of 126 children undergoing intravenous cannulation, VR distraction reduced procedural pain by 1.6 points on a 10-point scale and more than tripled the reduction in procedural anxiety relative to routine care. Nearly a quarter of children who used VR reported no pain at all and more than two-fifths ended the procedure free of anxiety, compared with very small minorities receiving routine care. The benefit survived adjustment for baseline anxiety, age and sex, was consistent across strata for anxiety and was graded by the degree of engagement with the virtual environment. Our results align closely with previous randomized trials in the specific setting of intravenous access. Gold *et al*. **[11]** studied immersive VR during peripheral intravenous catheter placement and found significant reductions in both pain and anxiety, mirroring the direction and approximate magnitude we observed. Yildirim and Gerceker **[12]** reported that VR during intravenous insertion in a paediatric emergency unit reduced procedure-related fear, anxiety and pain and additionally improved first-attempt insertion success, a downstream benefit plausibly mediated by the reduced movement and distress our data demonstrate. Lee *et al*. **[13],** using a domed ceiling screen rather than a head-mounted display in young children, likewise found lower procedural pain in the VR arm. Gerceker *et al*. **[14]** compared VR with a simpler stress-ball distractor during phlebotomy and found VR the more effective, a comparison of direct relevance to resource-limited services such as ours, where the practical choice is often between a modest technological investment and no structured distraction at all. The dose-response relationship we observed, in which greater engagement predicted both lower pain and greater anxiety relief, is strongly corroborated by Jain *et al.* **[15],** whose randomized trial in paediatric burn patients showed that game realism, fun and engagement significantly influenced self-reported pain, supporting immersion rather than mere device exposure as the operative mechanism. These convergent findings, obtained in health systems very different from our own, indicate that the attentional mechanism underlying VR analgesia is robust to setting and that the principal barriers to benefit are practical rather than physiological. The practical implication is that VR should not be treated as a device that is simply switched on: content must be matched to the child's age and preference, adequate priming before the procedure matters and a child who is visibly not absorbed is unlikely to benefit. From an implementation perspective, a cooperation rate of 98.4%, a single refusal and no cybersickness, fright or device-related harm indicate that a consumer headset can be deployed safely on a busy paediatric surgical ward with brief staff orientation, at a modest and non-recurring capital cost and with no consumables. Several limitations should be acknowledged. Blinding of participants and staff was impossible and expectancy effects may have inflated self-reported benefit; the study was conducted at a single centre, limiting generalisability. Baseline anxiety was unequally distributed despite alternate allocation, although adjusted analyses indicate this did not drive the result. Because pain was absent in all children before the procedure, within-child change in pain could not be analysed and a between-group post-procedure comparison was used. Anxiety was recorded as ordered categories mapped to an ordinal scale, which may lose granularity and the sex distribution was heavily skewed towards boys, so the apparently larger effect in girls rests on a small subgroup and must be regarded as hypothesis-generating. Only immediate outcomes were measured; whether a less distressing first experience reduces anticipatory anxiety at subsequent procedures was not assessed and is an important question for future work.

Conclusion:

Virtual reality distraction produced significantly lower procedural pain and substantially greater anxiety reduction than routine care in children aged 5-15 years undergoing intravenous cannulation. The benefit was independent of baseline anxiety, age and sex, was graded by the child's engagement with the virtual environment and was achieved with high acceptability and no device-related harm. Virtual reality is an effective, safe and practical non-pharmacological adjunct for painful and anxiety-provoking procedures in children, including in resource-constrained settings.

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