Distraction in the Emergency department using Virtual reality for INtravenous procedures in Children to Improve comfort (DEVINCI): a pilot pragmatic randomized controlled trial

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Abstract

Objectives Intravenous (IV) procedures cause pain and distress in the pediatric emergency department (ED). We studied the feasibility and acceptability of virtual reality distraction for patient comfort during intravenous procedures.

Methods Children were randomized to a control (standard care) or intervention group (standard care + virtual reality). Thresholds for feasibility and acceptability (primary outcomes) were determined through a priori established criteria. The level of procedural pain (principal clinical outcome) and distress, as well as memory of pain at 24 h were collected and reported as medians (Q1, Q3) for each group.

Results 63 patients were enrolled, with a high rate of recruitment (78.8%) and game completion (90.3%). Patients, parents and, healthcare providers reported high satisfaction levels. There were no serious adverse events. Five of the 30 patients (16.7%) exposed to virtual reality reported mild side effects. Self-reported procedural pain (verbal numerical rating scale: 3 (1, 6)/10 vs 3 (1, 5.5)/10, $p=0.75$) was similar between groups. Further exploratory clinical measures were reported for the intervention and control groups, respectively: self-rated distress during the procedure (Child Fear Scale: 1 (0, 2)/4 vs 2 (0, 3)/4); distress evaluated by proxy during the procedure (Procedure Behavior Check List: 8 (8, 9)/40 vs 10 (8, 15)/40); memory of pain at 24 h (VNRS: 2 (1, 3)/10 vs 4 (2, 6.5)/10).

Conclusion The addition of virtual reality to standard care is feasible and acceptable for pain and distress management during IV procedures in the pediatric ED. Occasional mild, self-resolving side effects were observed in the intervention group. Self-reported pain during the procedure was similar between groups.

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Keywords Pediatric · Emergency department · Procedural pain · Distress · Virtual reality · Distraction

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Résumé

Objectifs Les procédures intraveineuses (IV) causent de la douleur et de la détresse dans le service des urgences pédiatriques (ED). Nous avons étudié la faisabilité et l'acceptabilité de la distraction en réalité virtuelle pour le confort du patient lors des procédures intraveineuses.

Les méthodes Les enfants ont été randomisés dans un groupe de contrôle (soins standard) ou d'intervention (soins standard + réalité virtuelle). Les seuils de faisabilité et d'acceptabilité (résultats primaires) ont été déterminés au moyen de critères établis a priori. Le niveau de douleur procédurale (résultat clinique principal) et de détresse, ainsi que la mémoire de la douleur à 24 heures ont été recueillis et rapportés sous forme de médiane (Q1, Q3) pour chaque groupe.

Résultats 63 patients ont été inscrits, avec un taux élevé de recrutement (78,8 %) et de complétion du jeu (90,3 %). Les patients, les parents et les prestataires de soins de santé ont déclaré des niveaux de satisfaction élevés. Il n'y a pas eu d'événements indésirables graves. Cinq des 30 patients (16,7 %) exposés à la réalité virtuelle ont signalé des effets secondaires légers. La douleur procédurale auto-déclarée (échelle d'évaluation numérique verbale : 3 (1, 6)/10 vs 3 (1, 5,5)/10, $p = 0,75$) était similaire entre les groupes. D'autres mesures cliniques exploratoires ont été signalées respectivement pour les groupes d'intervention et de contrôle : détresse auto-évaluée pendant la procédure (échelle de peur de l'enfant : 1 (0,2) / 4 vs 2 (0, 3) / 4); détresse évaluée par procuration au cours de la procédure (Procedure Behavior Check List: 8 (8, 9)/40 vs 10 (8, 15)/40) ; mémoire de la douleur à 24 heures (VNRS : 2 (1, 3)/10 vs 4 (2, 6,5)/10).

Conclusion L'ajout de la réalité virtuelle aux soins standard est faisable et acceptable pour la gestion de la douleur et de la détresse pendant les procédures IV dans l'urgence pédiatrique. Des effets secondaires occasionnels légers et auto-régulants ont été observés dans le groupe d'intervention. La douleur auto-déclarée pendant l'intervention était similaire entre les groupes.

Clinician's capsule

What is known about the topic?

Virtual reality has shown promise for the management of procedural pain and distress in pediatric patients.

What did this study ask?

Is virtual reality added to standard of care a feasible and acceptable intervention for IV procedures in the pediatric ED?

What did this study find?

The addition of virtual reality was a feasible and acceptable intervention, but mild, self-resolving side effects were noted.

Why does this study matter to clinicians?

Incorporating virtual reality to the multi-modal management of procedural pain and distress is attainable in the pediatric ED.

Multimodal approaches [7–9], including physical, psychological and pharmacological strategies, have been proven to reduce pain and distress in patients undergoing intravenous (IV) procedures [10–12]. Distraction, which can improve patient experience, remains the most studied psychological intervention [13]. Due to its immersive nature, virtual reality has the potential to effectively distract patients from a “real world” negative experience. Its use in the healthcare setting has become more accessible due to the development of more portable and affordable systems. Potential side effects, such as dizziness, nausea, headache, are few and infrequent [14].

In this context, the aims of this pilot pragmatic randomized controlled trial (RCT) were twofold:

1. To determine the feasibility and acceptability of pediatric emergency department (ED)-based virtual reality distraction during IV procedures to manage pain and distress;
2. To estimate effect size and parameters to guide future clinical efficacy trial planning and power calculations.

Introduction

Inadequate pain management in children has significant consequences, such as greater pain perception and apprehension of future procedures [1, 2]. Suboptimal procedural pain management is consistently reported in the literature [3, 4], especially for procedures involving needles, which are a leading cause of pain in children [5, 6].

Methods

Design

This was a pragmatic pilot RCT using a parallel design with two groups.

The Institutional Research and Ethics Board reviewed and approved the study. Written consent (parents) and assent (children) was obtained by the research nurses.

Setting

The research was conducted in a single ED of a tertiary care pediatric hospital (> 80,000 annual visits), from December 2018 to April 2019.

Sample

Children between 7 and 17 years old requiring an IV procedure (IV insertion or venipuncture) were recruited. The exclusion criteria were: (1) unstable patient or urgent procedure required; (2) important cognitive impairment (e.g. severe autism spectrum disorder) precluding game use; (3) diagnosis of epilepsy or seizures; (4) parental/legal guardian unavailability; and (5) inability to speak French or English.

Measures of outcome variables

Feasibility of the study process was assessed by documenting the following outcomes:

- Recruitment feasibility: percentage of eligible patients/parents agreeing to participate in the study and time to access the target sample size.
- Intervention feasibility: proper functioning of the game and the coordination of the virtual reality with IV procedure. The game had to be available and operational for the whole procedure

Acceptability was assessed through satisfaction surveys, using a 0–10 numerical rating scale, among patients, parents, and the healthcare providers performing the IV procedure and about their willingness to use the virtual reality device in subsequent IV procedures. The occurrence of serious adverse events and side effects in both groups, as well as completion of the virtual reality game, were also documented.

A priori feasibility and acceptability criteria were established following experts' consensus including nurses and physicians working in the pediatric ED were:

- a) 80% of families approached for recruitment consent to participate;
- b) 80% of recruited patients finish the game as planned (intervention group);
- c) Mean > 7 on the 0–10 satisfaction scale (patients, parents, and healthcare providers);
- d) No serious adverse events related to the virtual reality (injury, agitation, vomiting, severe dizziness, convulsion);

Pain intensity and distress were selected as clinical outcomes based on guidelines from the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (PedIMPACT) [15]. The principal clinical outcome was the self-reported pain level during the procedure, measured with the verbal numerical rating scale, where patients were asked to indicate the intensity of their pain between 0 (no pain) and 10 (worst pain ever felt) [16, 17]. This outcome was measured within 2 min of the end of the procedure by asking the child to rate their level of pain during the procedure (Fig. 1).

Secondary clinical outcomes measures included:

- A self-reported measure of anxiety with the Child Fear Scale [18], for specific use in children undergoing painful experiences [scale with five faces ranging from 0 (no fear) through 4 (extremely fearful)].
- Proxy evaluation of procedure-related distress using the Procedure Behavior Check List by the research nurse [19]. It consists of eight items scored between 1 and 5, for a total between 8 and 40 [20]. Procedure Behavior Check List was determined by a single rater per patient. All raters were trained research nurses who had used this scale in prior studies.
- Baseline and post-procedural pain score measured by the verbal numerical rating scale; the latter was measured at 5 min after the end of the procedure;
- Memory of pain using the verbal numerical rating scale measured 24 h after the procedure. Parents were contacted by phone or text message and required to ask their child to rate their recall of the pain experienced during the procedure.

Demographic and clinical characteristics were also recorded using a standardized data collection form.

Allocation and randomization

Patients were allocated (1:1) to either group according to a computer-generated block randomization (block sizes 4, 6, 8) [21]. Once a patient was recruited in the study, a sealed envelope containing the allocation was opened by the research nurse.

Group interventions

Patients were randomized to either of the following two groups:

- a) Control group: patients in this group were offered the local standard of care with respect to IV procedures. Typically, parental presence is encouraged, topical anes-

VNRS: Verbal Numerical Rating Scale (Self-reported pain level, 0–10);

CFS: Child Fear Scale (Self-reported anxiety, 0–4);

PBCL: Procedure Behavior Checklist (Proxy evaluation of distress, 8–40).

Fig. 1 Timeline of the data collection process. VNRS Verbal Numerical Rating Scale (Self-reported pain level, 0–10), CFS Child Fear Scale (Self-reported anxiety, 0–4), PBCL Procedure Behavior Checklist (Proxy evaluation of distress, 8–40)

thetic (Maxilene®—Liposomal lidocaine 4%) is offered, and distraction is usually done by the parent or by the healthcare provider performing the procedure. However, despite numerous teaching sessions, formal guidelines, educational videos and posters, positioning remains variable depending on provider comfort.

- b) **Intervention group:** patients in this group were offered the local standard of care in addition to virtual reality distraction through the use of Oculus Rift® in a sitting position (Online Appendix 1). We used the videogame Dreamland®, developed by Oniric Interactive in collaboration with the Université du Québec en Abitibi-Témiscamingue, a classic “point & shoot” game that uses head movements for aiming and a hand trigger for shooting balloons [22]. It is tailored to children’s developmental stages, and designed to maximize the feeling of immersion, while minimizing cybersickness symptoms. Oculus Rift® is a virtual reality tool that provides a wide field of view, high resolution display, integrated 3D audio and motion detection. A 3-min familiarization period was allotted prior to the IV procedure (Online Appendix 2).

Sample size

To determine the feasibility and acceptability of the virtual reality in the pediatric ED, a convenience sample size of 60 patients was deemed sufficient following expert consensus among pediatric ED physicians and the clinical researchers involved with the study.

Recruitment procedures

Eligible patients were identified after triage using the local ED information management system, weekdays between 8 AM and 8 PM. Parents of eligible children were approached in the pediatric ED for consent and assent. Patients were then informed of their assignment to the virtual reality or control group.

Data analysis plan

Analyses were conducted using the statistical analysis software SPSS version 25.0 (IBM Corporation, New York, USA). Descriptive statistics were performed for demographic and clinical variables. As all continuous variables (except age) were non-normally distributed based on the

Shapiro–Wilk test, they were described using the median, interquartile range (IQR) and 95% confidence interval (CI) [23]. Categorical variables were expressed as proportions. Differences between groups on levels of pain and distress (verbal numerical rating scale, Child Fear Scale, Procedure Behavior Check List) at different study time points were reported with corresponding measures of spread. As this was a pragmatic pilot RCT, tests of statistical significance were not reported for non-primary outcomes, except for pain during the procedure (principal clinical outcome). For all other results, a level of $p < 0.05$ was selected for the threshold of statistical significance.

Results

Feasibility and acceptability

Ninety-seven (97) families were screened for participation to this study. Seventeen did not meet the inclusion criteria.

Eighty (80) families were approached and 63 (78.8%) agreed to participate to the study (Fig. 2). One patient randomized to the intervention group was excluded as the IV procedure was cancelled following randomization. The target sample size was reached in less than 5 months.

Baseline participant characteristics are summarized in Table 1. Both groups were similar in most characteristics, except for 'position during venipuncture' which showed a higher proportion of children sitting in the virtual reality group, as this was required to be able to use the device (100% vs 69.2%). Most patients (74.2%) did not receive any oral or intranasal analgesics prior to the procedure, but most of them (77.4% in virtual reality group vs 61.3% in control group) received a topical anaesthetic.

The virtual reality system could not be used due to an unforeseen software update in the intervention group in one patient. No serious adverse event was reported in either group. No side effect was reported in the control group. Five of the 30 patients (16.7%) who were exposed to virtual reality reported mild side effects (dizziness, $n = 3$; nausea, $n = 1$;

Fig. 2 CONSORT flow diagram of patients in the DEVINCI pilot pragmatic RCT. ¹Reasons for refusal included: parent's and/or child's reluctance to answer study questions ($n = 2$), lack of interest for the research project ($n = 2$), dislike of video games or virtual reality ($n = 5$), unwillingness to expose child to additional screen time ($n = 1$), unwillingness to potentially prolong ED stay (although the consent form explained that participation in the study was unlikely to prolong ED stay); $n = 5$), patient's desire to see the procedure ($n = 2$)

Table 1 Sample characteristics

	Intervention ^a <i>n</i> = 31	Control ^b <i>n</i> = 31
Mean age, years (SD)	11.1 (2.9)	12.3 (3.0)
Female (%)	20/31 (64.5)	18/31 (58.1)
Prior IV (%)		
0	10/29 (34.5)	9/29 (31)
1–9	16/29 (55.2)	13/29 (44.8)
> 9	3/29 (10.3)	7/29 (24.1)
Venipuncture type (%)		
Blood test	23/31 (74.2)	21/28 (75)
IV catheter	2/31 (6.5)	3/28 (10.7)
Both	6/31 (19.4)	4/28 (14.3)
Positioning (%)		
Sitting	27/27 (100)	18/26 (69.2)
Lying on back	0 (0)	8/26 (30.8)
Topical anesthetic (%)		
Yes	24/31 (77.4)	19/31 (61.3)
No	7/31 (22.6)	12/31 (38.7)
Prior oral/intra-nasal analgesic (%) ²		
Yes	8/31 (25.8)	8/31 (25.8)
No	23/31 (74.2)	23/31 (74.2)
Physical restraint (%)		
Yes	5/31 (16.1)	10/30 (33.3)
Degree of restraint		
Low	4/5	9/10
Moderate	1/5	0/10
High	0/5	1/10
IV Site (%)		
Dorsum of hand	4/31 (12.9)	4/30 (13.3)
Antecubital	24/31 (77.4)	23/30 (76.7)
Other	3/31 (9.7)	3/30 (10)

^aDenominators indicated to account for incomplete/absent data in each category

^bOf those who had prior analgesics, two patients (one in each group) received prior intranasal Fentanyl (1 mcg/kg), whereas all others received oral acetaminophen, ibuprofen, or both

headache, *n* = 1). The latter patient reported this symptom prior to enrolment and requested to end the virtual reality game prematurely (while the other four patients completed the game). Another patient insisted on seeing the procedure following the initiation of the virtual reality game, and therefore, requested to stop it prematurely. Overall, 90.3% (28/31) of the patients randomized to the intervention group completed the game as planned.

Overall satisfaction from patients, parents and healthcare providers was high in all groups (Table 2). Median (Q1, Q3) level of satisfaction was high among patients (9 (8, 10) /10 vs 8 (5.75, 10)/10, *p* = 0.057). At least ten different nurses and laboratory technicians performed the venipunctures.

Table 2 Median (Q1, Q3; 95% CI) level of satisfaction among patients, parents and healthcare providers^a

	Intervention	Control	<i>p</i> value ^b
Patients	9 (8, 10; 9, 10) <i>n</i> = 29	8 (5.75, 10; 8, 10) <i>n</i> = 30	0.057
Parents	10 (9, 10; 9, 10) <i>n</i> = 29	10 (9, 10; 9, 10) <i>n</i> = 28	0.831
Healthcare providers	10 (10, 10; 10, 10) <i>n</i> = 29	7 (5, 10; 6, 10) <i>n</i> = 24	< 0.001

^aMeasured on a 0–10 Verbal Numerical Rating Scale

^bIndependent samples Mann–Whitney *U* test

There was a higher level of satisfaction among these healthcare providers in the intervention group (10 (10, 10)/10 vs 7 (5, 10)/10, *p* < 0.001). Moreover, 28/30 (93.3%, 95% CI [84.4, 100]) healthcare providers indicated that they would like to use this technology (virtual reality) in future patient encounters.

Clinical outcomes

The median (Q1, Q3) level of pain during the procedure was not statistically different between the intervention and control groups, respectively (verbal numerical rating scale: 3 (1, 6)/10 vs 3 (1, 5.5)/10, *p* = 0.75). Self-rated distress during the procedure (Child fear scale) was 1 (0, 2)/4 in the intervention group vs 2 (0, 3)/4 in the control group. Distress evaluated by proxy during the procedure (Procedure Behavior Check List) was 8 (8, 9)/40 in the intervention group vs 10 (8, 15)/40 in the control group, whereas memory of pain at 24 h (verbal numerical rating scale) was 2 (1, 3)/10 vs 4 (2, 6.5)/10, respectively (Table 3).

The IV procedure was successful on the first attempt in 23/31 (74.2%) patients in the intervention group and 15/30 (50%) patients in the control group. The healthcare provider level of experience was > 5 years in the vast majority of IV procedures (> 88%), which was similar between groups.

Discussion

This pilot pragmatic RCT showed that the addition of a virtual reality-based distraction to standard of care was a feasible and acceptable intervention during IV procedures in a pediatric ED. The recruitment rate was slightly lower (78.7%) than the expected threshold (80%) established a priori, but the relatively short time to the target sample size reflects a keen interest of patients, parents, and healthcare providers for this technology. Among the patients who were exposed to virtual reality, 16.7% reported side effects, which were mild and self-resolving. A majority (90.3%) of patients randomized to the intervention group finished the game as

Table 3 Median (Q1, Q3; 95% CI) procedural pain and distress at different study time points

	Intervention <i>n</i> = 31	Control <i>n</i> = 31
Self-reported pain level (verbal numerical rating scale, 0–10)		
Baseline	4 (1, 5; 2, 5)	3 (0, 4; 0, 4)
During the procedure	3 (1, 6; 2, 4)	3 (1, 5.5; 2, 5) ^a
Post-procedure	0 (0, 2; 0, 1)	1 (0, 3; 0, 2)
Memory of pain at 24 h	2 (1, 3; 1, 3) <i>n</i> = 23	4 (2, 6.5; 2, 5) <i>n</i> = 24
Self-reported anxiety (Child fear scale, 0–4)		
Baseline	2 (1, 3; 1, 2)	1 (0, 3; 0, 2)
During the procedure	1 (0, 2; 1, 1)	2 (0, 3; 1, 3)
Post-procedure	0 (0, 0; 0, 0)	0 (0, 1; 0, 0)
Proxy evaluation of distress (Procedure Behavior Check List, 8–40)		
Baseline	8.00 (8, 10; 8, 9)	8.00 (8, 10; 8, 9)
During the procedure	8.00 (8, 9; 8, 9)	10.00 (8, 15; 9, 14)

^a*p* value = 0.75 (calculated with the independent samples Mann–Whitney *U* test)

planned. No serious adverse events were observed. Most healthcare providers caring for patients in the intervention group declared they would use the virtual reality device in subsequent episodes of care. As virtual reality systems get smaller, more portable, and no longer require a computer to run the game, integration into workflow may be further facilitated.

Results showed no significant difference in pain score during the procedure, our principal clinical outcome. As for procedural distress, proxy and self-rated scores were lower in the virtual reality group. Recall of pain at 24 h was also lower in the virtual reality group, which suggests that virtual reality might have a beneficial effect on children's recall of the painful procedure. However, these secondary outcomes remain exploratory given the study design.

Immersive virtual reality has been documented in different settings and showed very promising results [14, 24–26], including a study in the ED involving IV procedures in children [27]. A recent systematic review summarized the clinical effects of virtual reality in different pediatric applications, with numerous reports of reduced procedural pain and distress [28]. It is hypothesized that virtual reality might block nociceptive impulse through intercortical modulation, as demonstrated by magnetic resonance imagery, by diverting the child's attention to a more positive stimulus [25]. A beneficial effect of virtual reality on memory of pain was also observed in a pilot study performed by some of the co-authors [29].

As this was a pragmatic trial, virtual reality was used in addition to standard of care, therefore, allowing for less control on co-interventions used as standard of care [30]. The widespread use of topical anaesthetic prior to needle procedures probably led to lower procedural pain levels in both groups, which likely contributed to the lack of clinical effectiveness on procedural pain, in contrast with prior

reports. In this context, procedural distress may represent a more meaningful primary clinical outcome for future trials assessing distraction modalities during painful pediatric procedures, particularly when a topical anesthetic is used for pain management. In addition, pilot studies are not adequately powered to detect a difference between groups; rather, we conducted an exploratory investigation of the intervention on pain level.

Results from our trial must be interpreted within the study limitations. This pilot pragmatic RCT was performed in a single pediatric ED and aimed to evaluate feasibility and acceptability rather than efficacy of the intervention. Moreover, blinding of the research nurses was not feasible due to the use of a virtual reality head-mounted device, which may have yielded higher satisfaction levels or lower distress levels in the intervention group, given that some measures were observational. Also, there was a significantly higher proportion of patients sitting in the intervention group, given the requirements of the virtual reality system. This position is promoted to increase comfort of pediatric patients during IV procedure and to decrease distress [31–36]. Nonetheless, some patients preferred the lying position in our control group. Likewise, a higher proportion of patients were physically restrained in the control group, which may have led to higher pain and distress scores in the control group. However, directionality cannot be determined with certainty, as it may be that patients in the intervention group were less restrained because they experienced less distress.

Conclusion

Overall, virtual reality seems to be a feasible, acceptable and appealing intervention for the management of pain and distress during IV procedures in the pediatric ED. Occasional

mild side effects were observed. There was no difference in self-rated pain during the procedure, which was the principal clinical outcome.

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Author contributions EO elaborated the first draft of the protocol, its design and oversight; he elaborated the first draft of the manuscript, contributed to the statistical analysis, and approved the final manuscript. EDT supervised and revised the elaboration of the protocol, of the design and oversight; she supervised and reviewed the manuscript, and approved it prior to submission. BB reviewed the protocol, the design and oversight; he reviewed the manuscript, contributed strongly to the statistical analysis, and approved it prior to submission. ML contributed to the elaboration of the protocol and ethics approval process. She contributed to recruitment and study data collection and also reviewed the manuscript. MC reviewed the protocol; she reviewed the manuscript, and approved it prior to submission. CK reviewed the protocol, the design and oversight; she reviewed the manuscript, and approved it prior to submission. MS reviewed the protocol; she reviewed the manuscript, and approved it prior to submission. CT reviewed the protocol; she reviewed the manuscript, and approved it prior to submission. DP conceptualized and designed the virtual reality content used for this study. He also reviewed the manuscript and approved it prior to submission. CC-T contributed to the development of the virtual reality content used for this study. He also reviewed the manuscript, and prepared it for submission. SLM contributed to the redaction of the protocol and reviewed several iterations and the final version of the.

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Compliance with ethical standards

Conflict of interest The virtual reality system used during this study was lent to the research team by Oniric Interactive. A representative of this company also trained the research coordinators. One of the study authors (DP) conceptualized and designed the virtual reality game used for this study. This author contributed to the manuscript by providing technical expertise, but did not participate in the study design, in the evaluation of patients, or in the data analysis and interpretation. The corresponding author had full authority regarding the decision to submit for publication.

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