Original Article

A randomized trial of iPad distraction to reduce children's pain and distress during intravenous cannulation in the paediatric emergency department

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Abstract

Objectives: We compared the addition of iPad distraction to standard care, versus standard care alone, to manage the pain and distress of intravenous (IV) cannulation.

Methods: Eighty-five children aged 6 to 11 years requiring IV cannulation (without child life services present) were recruited for a randomized controlled trial from a paediatric emergency department. Primary outcomes were self-reported pain (Faces Pain Scale-Revised [FPS-R]) and distress (Observational Scale of Behavioral Distress-Revised [OSBD-R]), analyzed with two-sample t-tests, Mann–Whitney U-tests, and regression analysis.

Results: Forty-two children received iPad distraction and 43 standard care; forty (95%) and 35 (81%) received topical anesthesia, respectively ($P=0.09$). There was no significant difference in procedural pain using an iPad (median [interquartile range]: 2.0 [0.0, 6.0]) in addition to standard care (2.0 [2.0, 6.0]) ($P=0.35$). There was no significant change from baseline behavioural distress using an iPad (mean $\pm$ SD: 0.53 ± 1.19) in addition to standard care (0.43 ± 1.56) ($P=0.44$). Less total behavioural distress was associated with having prior emergency department visits (odds ratio [95% confidence interval]: $-1.90 [-3.37, -0.43]$) or being discharged home ($-1.78 [-3.04, -0.52]$); prior hospitalization was associated with greater distress ($1.29 [0.09, 2.49]$). Significantly more parents wished to have the same approach in the future in the iPad arm (41 of 41, 100%) compared to standard care (36 of 42, 86%) ($P=0.03$).

Conclusions: iPad distraction during IV cannulation in school-aged children was not associated with less pain or distress than standard care alone. The effects of iPad distraction may have been blunted by topical anesthetic cream usage.

Clinical trials registration: [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02326623): NCT02326623.

Keywords: Digital technology; Emergency department; Paediatrics; Tablet; Venipuncture

Received: April 21, 2020; Accepted: July 7, 2020

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Venipuncture and intravenous (IV) cannulation are common paediatric procedures and are associated with significant pain and distress (1–4). Memories of distress, needle phobia, and avoidance of future healthcare interventions can develop if pain is not adequately managed, especially for younger children (5–7).

Procedural pain and distress in children are often undertreated. The most common strategies used include pharmacotherapy and distraction. While anesthetic creams are generally very good at managing pain, they do not necessarily address procedure-associated distress (8–10). Anxiolytic agents and systemic analgesics can be associated with adverse effects and are not always available to clinicians (11,12). As such, there is a growing interest in psychological and physical approaches to pain and distress management that are effective and safe (13–15).

The Canadian Paediatric Society and the American Academy of Pediatrics have recommended device-related technology as an area to explore for pain and distress management (16–18). There is currently little research on iPad use directly by patients (19), even though iPads seem particularly well suited for distraction due to their versatility, portability, and ability to personalize the content.

Our primary objective was to assess the effect on pain and distress with iPad plus standard care versus standard care alone, in children undergoing IV cannulation in the emergency department (ED). The secondary and exploratory objectives were to (a) describe parent and healthcare provider satisfaction, (b) describe ease and success of procedure performance, as assessed by the clinical nurse, (c) evaluate parental anxiety related to their child's IV cannulation, and (d) examine any association between parental anxiety and children's pain and distress.

METHODS

Study design and setting

This two-arm parallel randomized controlled trial (RCT) was conducted at the Stollery Children's Hospital ED (Edmonton, Alberta), a tertiary care paediatric hospital with an annual census of approximately 50,000.

Population

A consecutive sampling of eligible patients aged 6 to 11 years old were recruited between October 7, 2015 and December 15, 2016. This age group was chosen as children in this age range (a) are able to reliably self-report pain with a single validated pain measurement tool (20) and (b) have higher baseline pain and distress levels and, as such, are most likely to benefit from distraction (21–23). Inclusion criteria were a need for IV cannulation, being fully conscious and alert, and a proficiency in English. Exclusion criteria were hearing or visual impairments,

neurocognitive delays, sensory impairment to pain, or at the discretion of the attending physician for urgent medical attention.

Intervention

Patients in both arms were offered topical anesthetic cream (4% lidocaine), at the discretion of the clinical team. In the intervention arm, a trained research assistant (RA) provided the child with an iPad prior to the start of the procedure and explained how to use it, if required. The choice of pre-loaded applications, games, and movies was guided by a child life specialist at study inception ([Supplementary Appendix 1](#)). iPads were held by the parent during the procedure. Children and parents selected from the available content and could switch activities at any time. The control group received standard care, which included any techniques normally used to comfort the child without involving electronic devices (e.g., physical comforting, verbal and emotional support). No restrictions were placed on how parents interacted with their child during the procedure, child positioning (seated or supine) was at the discretion of the clinical team inserting the IV, and child life specialists were not involved in the preparation or procedure for any included child.

The child was assigned, using a 1:1 ratio, to either the iPad plus standard care or standard care alone arm using the randomization feature of REDCap, an electronic data capture tool hosted and supported by the Women and Children's Health Research Institute (University of Alberta) (24). A randomization table with 160 codes (80 intervention and 80 standard of care) was generated using an electronic randomization program and an alternating block balanced approach. Block sizes of four and six were used. Allocation was concealed to RAs, ED staff, child, and parents until informed consent was obtained, after which each participant was assigned to one of the study arms. Due to the nature of the intervention, blinding was not possible for the children, parents, or research and ED staff (including video coders).

Outcome measures

Primary outcomes were patient pain and distress. Self-reported pain was measured using the Faces Pain Scale-Revised (FPS-R) (25). This scale depicts six faces expressing 2-point increases in pain from 0 (no pain) to 10 (maximum pain). Children were asked to rate their pain pre-procedure and during-procedure. Distress was measured as the mean score derived from two team members' (KM and AI) independent coding of video recordings of the Observational Scale of Behavioral Distress-Revised (OSBD-R), with a score range of 0 to 23.5 (26,27). The mean of their two scores was used for analyses. Coded behaviours include information seeking, crying, screaming, restraint, verbal resistance, emotional support, verbal pain, and flailing. Video coders received standardized coding training, coded the first 10% of the videos and received personalized feedback on their

performance, after which they coded the remaining videos. Videos were analyzed for continuous 15-second intervals pre-, during, and post-procedure (Phases 1 to 3) (26,27). Pre-procedure was defined as the 2 minutes before cleaning the IV site, during procedure was the total duration of the IV cannulation, and post-procedure was the 2 minutes after the last point of contact with the nurse. Video coders were blinded to study hypotheses.

Data collection

An RA assessed eligibility between 15:00 and 23:00, 7 days per week, and obtained written informed assent and consent. They then gathered demographic information and relevant medical history. The IV cannulation procedure was video recorded using an iPad tablet that was set up on a tripod by the RA and was focused on the full body of the child, beginning a minimum of 2 minutes before the cannulation began (defined as cleaning of the injection site). Before and immediately after the procedure (i.e., within 2 minutes of skin-piercing), the RA collected self-reported pain of the procedure from the child and administered the State Trait Anxiety Inventory-State (STAI-S, Form Y) to parents in order to evaluate parental anxiety related to their child's IV cannulation. Cardiorespiratory monitoring was also in place. The end of procedure was defined as the last point of contact with the staff nurse, which was taping the cannula into place with or without an arm board. Two minutes post-procedure, both the nurse and parents completed satisfaction questionnaires. Video recording continued for at least 2 minutes post-procedure. Only the first IV cannulation attempt was recorded. [Supplementary Appendix 2](#) outlines the protocol for data collection.

Statistical analysis

Analyses were conducted using SAS (version 9; SAS Institute, Cary, NC). The significance level was set at 0.05. An intention-to-treat approach was employed. For the primary outcomes of child-reported pain and observed behavioural distress, a change from baseline score was calculated for each child and the means or medians were compared between the two arms using the two-sample t-test or Mann–Whitney U-test for non-parametric distributions. Parental anxiety was compared with a Mann–Whitney U-test. Model-based analyses were conducted using multiple linear regression analyses. Regression analyses were conducted using pain, behavioural distress, and change in parental anxiety (separately) as the dependent variable. A full model was conducted first, followed by a reduced model.

Sample size and power

A two-tailed, two-sample Mann–Whitney test was conducted for the primary outcome of child-reported pain based on a previous trial (28). To detect a difference of one face

(equal to 2 points) on the FPS-R (the minimal clinically important difference) (29), given a Type I error of 0.05% and 80% power, 40 patients were required per arm. A two-tailed two-sample t-test was also conducted for observed behavioural distress (i.e., $SD=2.77$) (28). To detect an effect size of 0.6 (observed in the previous music trial), given a Type I error of 0.05% and 80% power, 35 patients were required per arm.

Ethics

The study was approved by the Health Research Ethics Board (University of Alberta) and was registered with [ClinicalTrials.gov](#) (NCT02326623).

RESULTS

Participants

Eighty-five children were enrolled; see [Supplementary Appendix 3](#) for CONSORT diagram. The two arms were comparable with respect to baseline demographic variables ([Table 1](#)).

Children in both arms used iPads at home with similar frequency; 74% (31 of 42) and 90% (39 of 43) used iPads many times per week or every day, 24% (10 of 42) and 5% (2 of 43) used iPads once or less than once per week, and 2% (1 of 42) and 5% (2 of 43) did not use iPads at home, in the iPad and standard care arms, respectively.

IV cannulation details

There were no significant differences between arms in terms of location or success of IV attempts; 88% (75/85) of study participants received topical anesthesia prior to IV cannulation. Multiple nurses ($n=55$) performed the IV cannulations with a median of 4.5 (IQR 3.0, 8.0) years of experience; the median years of experience did not differ between the iPad (5.5 IQR 3.0, 9.0) and standard care (4.0 IQR 2.5, 6.5) (see [Table 1](#)).

Primary outcome

We found no significant difference in child-reported pain between arms pre-procedure ($P=0.87$), during procedure ($P=0.35$), or in the difference between the two time points ($P=0.79$) ([Table 2](#)). Likewise, with child distress (as measured by the OSBD-R), we did not observe a difference pre-procedure ($P=0.30$), during procedure ($P=0.09$), post-procedure ($P=0.34$), in total distress ($P=0.31$), or in the difference between pre-procedure and during venipuncture ($P=0.44$) ([Table 2](#)). Even when we excluded children who had zero baseline distress, we did not find a significant difference between arms ([Table 2](#)). In a post hoc analysis, we analyzed pain and distress reduction for the subgroup of children who received topical anesthesia for IV cannulation; there was

Table 1. Demographic characteristics by group (n=85)

	Group, no. (%)	
	Standard care	iPad
Age, years, median (IQR)	7 (6, 10)	8 (7, 10)
Male sex	24 (56%)	21 (50%)
Ethnic minority	12 (28%)	14 (33%)
Weight, kg, median (IQR)	29.6 (25.4, 36.2)	27.3 (24.0, 34.2)
Baseline heart rate (beats/min), median (IQR)	103 (90, 125)	105 (92, 121)
Premature	6 (14%)	4 (10%)
Previous ED visit	36 (84%)	33 (79%)
Previous hospitalization	13 (30%)	16 (39%)
Previous IV placement or blood draw	33 (77%)	35 (83%)
Parental report of child distress during previous IV placements or blood draw		
1 (no distress)	3 (9%)	5 (14%)
2	10 (30%)	9 (26%)
3	9 (27%)	8 (23%)
4	5 (15%)	6 (17%)
5 (as distressed as possible)	6 (18%)	7 (20%)
Total	33	35
Parental report of child distress for previous medical procedures		
1 (no distress)	5 (12%)	8 (19%)
2	13 (30%)	10 (24%)
3	12 (28%)	12 (29%)
4	7 (16%)	5 (12%)
5 (as distressed as possible)	6 (14%)	7 (17%)
Total	43	42
Location of first IV attempt		
Antecubital fossa (right or left)	22 (51%)	26 (62%)
Dorsum hand (right or left)	20 (47%)	16 (38%)
Other	1 (2%)	0 (0%)
Successful first IV attempt	33 (77%)	31 (74%)
Use of topical analgesia	35 (81%)	40 (95%)

ED Emergency department; IQR Interquartile range; IV Intravenous.

still no statistically significant difference in pain or distress reduction.

In regression analyses, addition of iPad versus standard care alone was not a predictor of total behavioural distress, change in behavioural distress from baseline to during procedure, change in parental anxiety scores, or patient pain scores. Children had less total behavioural distress if they had previous ED visits (odds ratio [95% confidence interval {CI}]: $-1.90 [-3.37, -0.43]$) or were discharged home during the study visit ($-1.78 [-3.04, -0.52]$); they had greater total behavioural distress if they had prior hospitalization experience ($1.29 [0.09, 2.49]$) ([Supplementary Appendix 4](#)).

Other outcomes

Mean pre-procedure parental state anxiety measured by the 80-point STAI-S was not significantly different between the iPad (36.3 ± 9.1) and standard care (39.6 ± 12.6) arms ($P=0.24$). Further, mean post-procedure parental state anxiety was not significantly different between the iPad (33.0 ± 9.5) and standard care (36.3 ± 13.4) arms ($P=0.40$). Finally, the mean change in parental anxiety scores post-procedure compared to baseline was not significantly different between arms ($P=0.87$).

Mean child heart rate during the procedure did not differ between the iPad (119 ± 17.7) and standard care (116 ± 19.7)

Table 2. Self-reported pain and observed distress scores (n=85)

	Group			
	Standard care	iPad	Total	P value
Pain: FPS-R				
FPS-R (during procedure) (n=84)				
Mean (SD)	3.6 (2.9)	3.3 (3.6)	3.5 (3.2)	0.35 (MW)
Median (IQR)	2.0 (2.0, 6.0)	2.0 (0.0, 6.0)	2.0 (0.0, 6.0)	
FPS-R (pre-procedure) (n=85)				
Mean (SD)	3.0 (2.6)	3.0 (3.1)	3.0 (2.9)	(0.87 (MW)
Median (IQR)	2.0 (0.0, 4.0)	2.0 (0.0, 6.0)	2.0 (0.0, 4.0)	
FPS-R score change (during procedure minus pre-procedure) (n=84)				
Mean (SD)	0.62 (3.7)	0.29 (3.1)	0.45 (3.38)	0.79 (MW)
Median (IQR)	0.0 (−2.0, 2.0)	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)	
Distress: OSBD-R scores				
Weighted Phase 1 score (pre-procedure) (n=79), median (IQR)	0.00 (0.00, 0.31)	0.00 (0.00, 0.19)	0.00 (0.00, 0.22)	0.30 (MW)
Weighted Phase 2 score (during procedure) (n=80), median (IQR)	0.40 (0.15, 1.02)	0.15 (0.00, 0.73)	0.32 (0.00, 0.89)	0.09 (MW)
Weighted Phase 3 score (post-procedure) (n=76), median (IQR)	0.00 (0.00, 0.50)	0.00 (0.00, 0.28)	0.00 (0.00, 0.44)	0.34 (MW)
Total distress score (n=80)				
Mean (SD)	2.09 (3.01)	1.34 (2.20)	1.73 (2.67)	0.31 (MW)
Median (IQR)	0.74 (0.25, 2.79)	0.44 (0.09, 1.50)	0.64 (0.15, 2.38)	
Range	0.00 to 13.21	0.00 to 9.59	0.00 to 13.21	
Phase 2 – Phase 1 score (n=79), median (IQR)	0.22 (0.00, 0.54)	0.03 (0.00, 0.50)	0.15 (0.00, 0.54)	0.44 (MW)
OSBD-R scores (excluding those who had no distress during Phase 2)				
Total distress score (n=59)				
Mean (SD)	2.58 (3.16)	1.83 (2.52)	2.26 (2.91)	0.34 (MW)
Median (IQR)	0.98 (0.47, 3.30)	1.07 (0.43, 1.63)	1.00 (0.43, 2.96)	
Range	0.05 to 13.21	0.02 to 9.59	0.02 to 13.21	
Phase 2 – Phase 1 score (n=68), median (IQR)	0.27 (0.08, 0.67)	0.34 (0.05, 0.98)	0.32 (0.08, 0.79)	0.71 (MW)
Weighted Phase 2 score (during procedure) (n=36), median (IQR)	0.79 (0.40, 1.71)	0.15 (0.04, 1.60)	0.71 (0.15, 1.71)	0.56 (t)

FPS-R Faces Pain Scale-Revised; IQR Interquartile range; OSBD-R Observational Scale of Behavioral Distress-Revised; MW Mann–Whitney test; t t-test.

Table 3. Parent and nurse reflections on IV insertion experience

	iPad, n (%)	Standard care, n (%)	P value
Parents			
‘Satisfied/Very Satisfied’ with IV insertion (n=85)	37 (88)	36 (86)	0.69
‘Satisfied/Very Satisfied’ with pain management (n=85)	41 (98)	38 (90)	0.24
Desire to employ same pain management strategy in future (n=83)	41 (100)	36 (86)	0.03
Nurses			
Reported IV insertion as ‘Easy/Very Easy’ (n=83)	34 (83)	32 (76)	0.46
Satisfied/Very Satisfied’ with IV insertion (n=83)	32 (78)	34 (81)	0.86
Desire to employ same pain management strategy in future (n=82)	40 (98)	38 (93)	0.62

arms ($P=0.38$). Parent and nurse reflections on the IV insertion experience are reported in [Table 3](#).

DISCUSSION

Main findings

We found no difference in pain or distress with the addition of iPad to standard care. Parental anxiety scores were the same between arms and did not influence children's pain and distress. Parents in both study arms reported high satisfaction with both the IV procedure and their child's pain management, and all parents in the iPad arm wished to receive the same intervention in the future. Nurses reported similarly high satisfaction.

Previous studies with digital tablet technology have yielded mixed results. A paediatric ED trial of 98 children aged 3 to 12 years demonstrated significant reductions in IV insertion-related pain and distress using Ditto (a handheld electronic device which provides procedural preparation and distraction), as measured by caregivers and nurses; interestingly, child-reported pain was not significantly reduced ([30](#)). A non-randomized trial of 103 children aged 2 to 6 years undergoing immunizations found that iPad distraction significantly reduced parental perception of their child's anxiety ([31](#)). In another small RCT of 41 children aged 4 to 11 years receiving injections in a clinic, self-reported and observed pain was higher in the tablet arm ([32](#)). Further, an RCT of 200 inpatient children found that playing a tablet game was no better at reducing perceived pain than nurse-delivered distraction during venipuncture ([33](#)). It seems that when children are asked *directly* about their pain, they report no difference with tablet-based distraction, even though healthcare providers or caregivers may report otherwise. This underscores the importance of direct child report over surrogate measures.

Most children in our study had mild or no pain with the procedure and almost all study participants received topical anesthesia prior to IV cannulation. We did not exclude use of topical anesthetic because it is known to be effective ([8–10](#)) and is commonly offered to children in many EDs, including ours. Further assessment of the isolated effect of digital technology may be ascertained through future network meta-analyses, to overcome the ethical constraints of limiting the use of a known effective agent.

Interestingly, iPads no longer appear to have the novelty they once did, considering that 96.5% of our cohort used electronic devices at home. As such, iPads may be insufficiently novel for technology-savvy children who are also distressed and may explain the lack of effect of the iPads demonstrated in our study. Given the literature and our findings, the use of iPad distraction in addition to standard of care (including topical analgesia) is not yet supported by evidence regarding the effect on pain and

distress for IV insertion. If used, local infection prevention and control advice regarding sanitizing of equipment should be followed. Exploration of other novel forms of technology-based distraction such as robots should also be considered, as they are more immersive, but their efficacy is currently less studied ([34](#)).

Limitations

Although we attempted to select age-appropriate and popular games and activities, they may not have appealed to all the children in the study, which may have reduced the effectiveness of iPad distraction. We did not record which specific games or activities each child engaged in. As such, we were not able to comment on the effect of active (e.g., popping bubbles) versus passive (e.g., watching a movie) activities. A number of patients had pain at baseline, and this pain may have distracted the children's attention to the additional pain of the IV cannulation. While having baseline pain is clinically common in the ED, it may not generalize to other settings in which the IV cannulation is elective, and the child is not in pain prior to the procedure (e.g., preparation for an elective procedure).

CONCLUSION

We did not find evidence that the use of an iPad was associated with less pain or distress during IV cannulation compared to standard care in children aged 6 to 12 years. The effects of iPad distraction may have been blunted by the effectiveness of topical anesthetic cream and our experienced paediatric ED clinical team. Future trials should explore more novel technology-based distraction for children's painful procedure management, with a focus on family-centred outcomes including satisfaction and comfort.

SUPPLEMENTARY DATA

Supplementary data are available at *Paediatrics & Child Health* Online.

ACKNOWLEDGEMENT

This work was presented at the Canadian Association of Emergency Physicians Annual Meeting (Calgary, Alberta) on May 30, 2018 as an oral presentation.

Funding: This study was supported by the Women & Children's Health Research Institute (Edmonton, Alberta, Canada) through the generous support of the Stollery Children's Hospital Foundation, in the form of a Supporting Platform in Research Grant, secured by SA and SC. LH is supported by a Canada Research Chair in Knowledge Synthesis and Translation, and is a Distinguished Researcher with the Stollery Science Lab. SS is supported by a Canada Research Chair in Knowledge Translation in Child Health, and is a Distinguished Researcher with the Stollery Science Lab.

Potential Conflicts of Interest: All authors: No reported conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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