Canadian Journal of Emergency Medicine (2021) 23:85–93
https://doi.org/10.1007/s43678-020-00023-5

ORIGINAL RESEARCH

A randomized trial of robot-based distraction to reduce children's distress and pain during intravenous insertion in the emergency department

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Received: 26 April 2020 / Accepted: 8 August 2020 / Published online: 10 December 2020

Abstract

Objectives Our objectives were to evaluate the effectiveness of humanoid robot-based distraction on reducing distress and pain in children undergoing intravenous insertion.

Methods A two-arm, open-label randomized controlled trial was conducted April 2017–May 2018, in a pediatric emergency department (ED). A sample of 86 children aged 6–11 years who required intravenous insertion were recruited. Exclusion criteria included hearing/visual impairments, neurocognitive delay, sensory impairment to pain, previous enrollment, and ED clinical staff discretion. Outcome measures included the Observed Scale of Behavioral Distress-Revised (OSBD-R) (distress) and the Faces Pain Scale-Revised (FPS-R) (pain).

Results Of the 86 children recruited (median age 9 years, IQR 7,10); 55% (47/86) were male, 9% (7/82) were premature, 82% (67/82) had a previous ED visit, 31% (25/82) had a previous hospitalization and 78% (64/82) had previous intravenous insertion. Ninety-six percent (78/81) received topical anesthetic prior to intravenous insertion. Total OSBD-R distress score was 1.49 ± 2.36 (standard care) versus 0.78 ± 1.32 (robot) ($p < 0.05$). FPS-R pain score was 4 (IQR 2,6) (standard care) versus 2 (IQR 0,4) (robot) ($p = 0.13$). Parental anxiety immediately after the procedure was 36.7 (11.1) (standard care) versus 31.3 (8.5) (robot) ($p = 0.04$). Parents were more satisfied with pain management in the robotic distraction group (95% vs 72% very satisfied) ($p = 0.002$).

Conclusions Humanoid robot-based distraction therapy is associated with a modest positive impact on child distress for pediatric intravenous insertion, but not pain. It can be considered a potential tool in the ED toolkit for procedural pain-associated distress reduction.

Clinical trial registration Clinicaltrials.gov Identifier: NCT02997631.

Keywords Pain · Venipuncture · Robot · Distress · Distraction

This study was presented as a poster at the Canadian Pediatric Society Annual Meeting (Toronto, Ontario, June 2019) and the Canadian Association of Emergency Physicians Annual Meeting (Halifax, Nova Scotia, May 2019), where it was awarded the 2019 Top Pediatric Abstract Award.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s43678-020-00023-5) contains supplementary material, which is available to authorized users.

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Résumé

Objectifs Nos objectifs étaient d'évaluer l'efficacité de la distraction robotique humanoïde pour réduire la détresse et la douleur chez les enfants subissant une insertion intraveineuse.

Méthodes Un essai contrôlé randomisé ouvert à deux bras a été mené d'avril 2017 à mai 2018, dans un service d'urgence pédiatrique. Un échantillon de 86 enfants âgés de 6 à 11 ans ayant besoin d'une insertion intraveineuse a été recruté. Les critères d'exclusion comprenaient des déficiences auditives / visuelles, un retard neurocognitif, une déficience sensorielle de la douleur, une inscription antérieure et la discrétion du personnel clinique des urgences. Les mesures des résultats comprenaient l'échelle d'hétéro-évaluation comportementale (OSBD-R: Observational Scale of Behavioral Distress – Revised) (détresse) et l'échelle de visages (FPS-R: Faces Pain Scale-Revised) (douleur).

Résultats Sur les 86 enfants recrutés (âge médian 9 ans, IQR 7,10) ; 55 % (47/86) étaient de sexe masculin, 9 % (7/82) étaient prématurés, 82 % (67/82) avaient une visite antérieure aux urgences, 31 % (25/82) avaient déjà été hospitalisés et 78 % (64/82) avaient déjà été insérés par voie intraveineuse. Quatre-vingt-seize pour cent (78/81) ont reçu une anesthésie topique avant l'insertion intraveineuse. Le score total de détresse OSBD-R était de 1,49 ± 2,36 (soins standard) contre 0,78 ± 1,32 (robot) ($p < 0,05$). Le score de douleur FPS-R était de 4 (IQR 2,6) (soins standard) contre 2 (IQR 0, 4) (robot) ($p=0,13$). L'anxiété parentale immédiatement après l'intervention était de 36,7 (11,1) (soins standard) contre 31,3 (8,5) (robot) ($p=0,04$). Les parents étaient plus satisfaits de la gestion de la douleur dans le groupe de distraction robotique (95 % vs 72 % très satisfaits) ($p = 0,002$).

Conclusions La thérapie de distraction à base de robot humanoïde est associée à un impact positif modeste sur la détresse de l'enfant pour l'insertion intraveineuse pédiatrique, mais pas la douleur. Il peut être considéré comme un outil potentiel dans la boîte à outils des Services d'Urgences pour la réduction de la détresse associée à la douleur procédurale.

Clinician's capsule

What is known about the topic?

Intravenous insertion is the most common, painful ED procedure for children and distraction therapy can effectively reduce their distress.

What did this study ask?

This study asked if adding robot-based distraction to the care of children undergoing intravenous placement lessened pain and distress.

What did this study find?

Robot-based distraction during intravenous insertion in school-aged children reduced child distress but not pain, compared to standard care, alone.

Why does this study matter to clinicians?

If available, robot-based distraction is an effective tool that we can add to our ED distress-reducing toolkit for procedural pain in children.

Introduction

Intravenous (IV) insertion and venipuncture are the most frequently performed invasive procedures in the emergency department (ED) setting [1] and are also the most painful experiences that children recall [2]. Inadequate pain management can result in needle phobia, fear, and dissatisfaction for families and healthcare providers [3, 4]. Current strategies for pain management in the ED include topical anesthesia and psychological approaches [5].

A systematic review of psychological interventions for needle-related procedures found they reduced children's self-reported pain [6]. Recent research confirms that technology-based devices can reduce distress and pain [7], and pediatric societies have recommended advanced digital technology as an area of exploration for distress and pain management [8]. Our goal was to determine if a potentially more immersive, less commonly-encountered technology could increase the positive impact of digital technology for children's pain experiences. Our study objective was to assess the effect of adding humanoid robot-based distraction to standard care on distress and pain for children undergoing IV insertion in the ED.

Patients and methods

Full trial protocol is published [9].

Study design and time period

A two-arm, open-label, parallel randomized controlled trial (RCT) with 1:1 allocation of patients was conducted at the Stollery Children's Hospital ED (Edmonton, Alberta), a tertiary care pediatric hospital with an annual census of 50 000. Trial registration (clinicaltrials.gov, NCT02997631) was completed prior to patient recruitment which took place April 2017–May 2018. This study was approved by the Health Research Ethics Board (University of Alberta).

Population

Eligible children were between the ages of 6–11 years, required IV placement, and had a normal level of consciousness. Exclusion criteria were hearing or visual impairments, neurocognitive delay, sensory impairment to pain, previous enrollment in the study, inability to follow study instructions in English and at the discretion of the clinical staff for urgent medical attention.

Intervention

All children received standard medical care (generally including a topical anesthetic cream) and those in the robot group received the additional intervention (robot) during IV insertion (Fig. 1).

The robot was programmed for children 6–11 years, using cognitive behavioral therapy-based strategies, and the same programming was delivered to all children. The robot began by introducing itself and asking the child to join in some simple activities, followed by deep breathing exercises. Following completion of the procedure, the robot made supportive comments stating how brave the child was, proceeded to dance to a popular song, and finished with a demonstration of Tai Chi. 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 and Child Life Specialists were not involved in the preparation or procedure for any included child.

Blinding and randomization

Randomization was determined using REDCap's secure online randomization tool [10]. A randomization table with 160 codes was generated by a statistician using an alternating block balance approach with block sizes of four and six. The table was then inputted into REDCap's randomization module. Research assistants accessed the computer-generated random assignment after consent and assent was obtained. Allocation was concealed from research staff, nurses, parents and children until consent was obtained and randomization was complete.

Data collection

A trained research assistant approached consecutive patients and conducted eligibility assessments. All participants provided written informed consent (caregiver) and assent (child). Figure 2 outlines the protocol used for data collection. Within 2–5 min of the start of the procedure (defined as cleaning of the injection site), the research assistant began recording the video and collected the Faces Pain Scale—Revised (FPS-R) (child) and State Trait Anxiety Inventory—State Scale Revised (STAI-S) (parent). For children randomized to the intervention group, the research assistant brought in the robot and explained how to interact with it. The clinical nurse then prepared for IV line placement while the research assistant placed an oxygen saturation monitor contralateral to the insertion site. The end of the procedure was the last point of contact with the clinical nurse (i.e. taping the cannula in place). Immediately following the IV insertion, the research assistant collected the second FPS-R (child) and STAI-S (parent). The clinical nurse and parent

Fig. 1 Robot and child

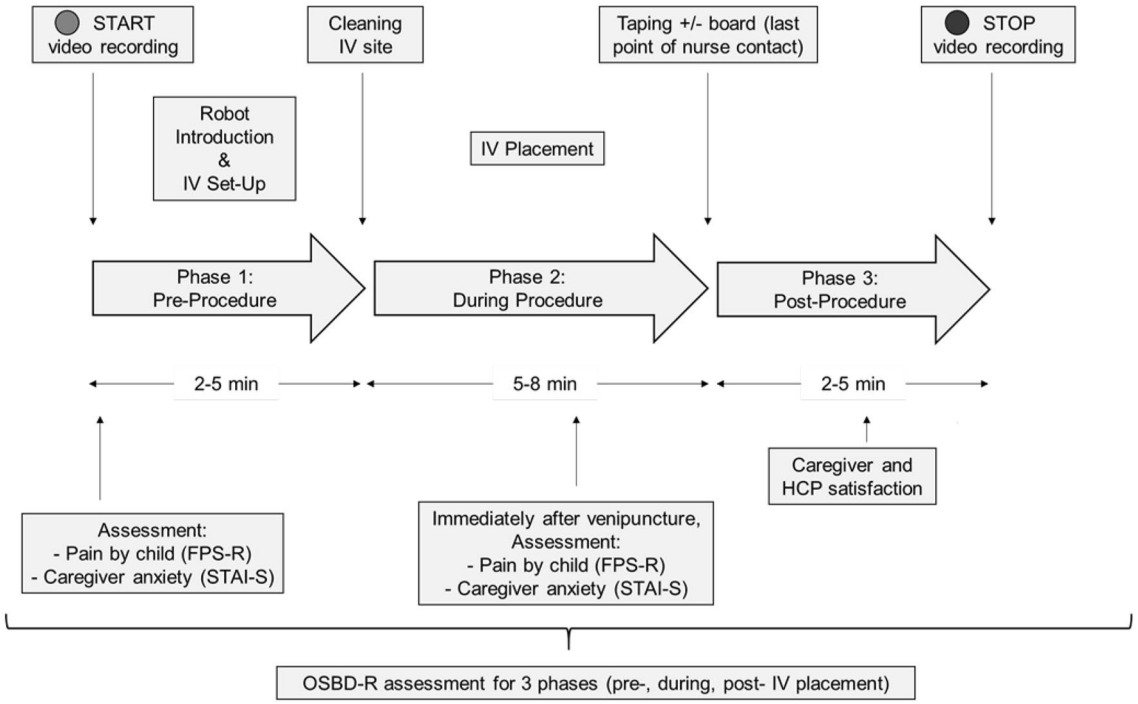

Fig. 2 Study flow diagram. *FPS-R* Faces Pain Scale—Revised; *STAI-S* State Trait Anxiety Inventory, Form Y (State Anxiety); *OSBD-R* Observed Scale of Behavioural Distress—Revised

then completed satisfaction questionnaires. Video recording concluded 2–5 min after the procedure and only one attempt was recorded, regardless of success of the IV insertion. Additional attempts occurred after the study protocol was completed and all measurements obtained.

Outcome measures

The primary outcomes were patient distress measured using the Observed Scale of Behavioural Distress-Revised (OSBD-R) [11] and pain using the FPS-R [12]. The OSBD-R is the most common measure of distress in procedure-related studies [13]. This previously validated tool analyzes eight distress related behaviours before, during and after the procedure [11]. Two research assistants were trained in the use of the tool and independently observed a video of each child while recording the frequency of operationally defined distress-related behaviors during continuous 15 s intervals before, during and after the procedure. Retraining and feedback was provided once 10% of videos were coded, to ensure the highest inter-rater reliability (Cohen's Kappa statistic = 0.88). The average of their two scores was used for analyses. The total overall weighted OSBD-R score (our primary distress outcome) is the sum of the OSBD-R scores for all eight behaviours, with a total score ranging from 0 (no distress) to 23.5 (maximum distress). The FPS-R is recommended for pain evaluation with strong evidence of validity and reliability in our age range [12]. Pain scores were self-reported by children and recorded for two time-points: before and during IV insertion, with during insertion being the primary pain outcome for this study.

The secondary outcomes were (a) to compare parental anxiety before and immediately after the procedure and (b) to examine any association between parental anxiety and child outcomes. Parental anxiety was measured using the STAI-S [14], a psychological inventory consisting of 40 self-report items with good psychometric properties [14].

Sample size

Sample size calculations were conducted using a two-tailed, two sample Mann–Whitney test for the primary outcome of child-reported distress and pain based on a previous distraction trial [15]. Sample size calculations were performed for observed behavioral distress using a two-tailed, two sample *t* test and data from a previous music trial (i.e. SD = 2.77) [15]. To detect an effect size of 0.6, given a Type I error of 0.05 and 80% power, 35 patients were required per study group. To detect a 2-point difference on the FPS-R (considered clinically important) [16, 17], given a Type I error of 0.05 and 80% power, 40 patients were required in each study arm. Total sample size for the trial was 80.

Data analysis

Statistical analyses were conducted using SAS version 9 (SAS Institute). Baseline variables were described using appropriate summary statistics. Binary outcomes were compared between groups using Fisher's exact test while ordinal outcomes (i.e. satisfaction) were analyzed using the Mann–Whitney test. For observed behavioral distress, a change from baseline score was calculated (during procedure minus pre-procedure) for each child and mean scores were compared between study groups using the Mann–Whitney *U* test. For child-reported pain during the procedure, mean scores were compared between groups using independent sample t-tests (for outcomes that were approximately normal) or Mann–Whitney *U* tests (for skewed data). Additional model-based analyses (multiple linear regression using backwards elimination) were conducted with distress or pain as the response variable. Primary analysis was based on an intention-to-treat approach. Similar approaches were used to compare study groups with respect to secondary outcomes. For all analyses, a p-value of 0.05 was considered to be statistically significant.

Results

Participants

Eighty-six patients were enrolled with 43 children in each arm of the study; 42 were analysed in the robot arm and 39 in the standard care arm. Four patients who did not receive the allocated intervention had their clinical plans changed by the clinical team (e.g. procedure cancelled), and one consented parent withdrew consent when the child's second parent relayed delayed concerns about confidentiality related

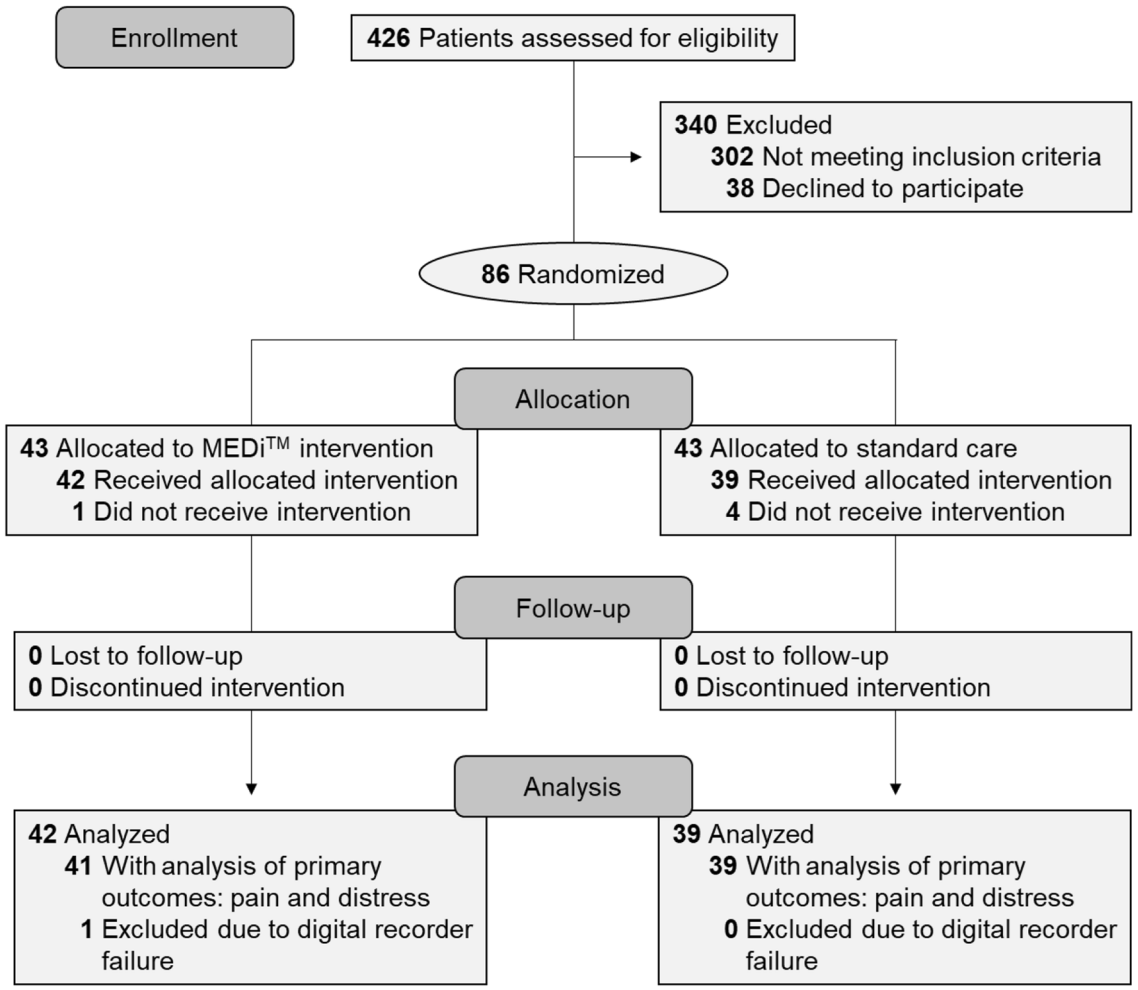

Fig. 3 CONSORT diagram. *The 5 patients who did not receive the allocated intervention had their clinical course altered by the clinical team for reasons unrelated to the study (e.g. no longer needed the IV) (n = 4) or due to withdrawn consent for confidentiality concerns, unrelated to study arm (n = 1)

Table 1 Demographic characteristics by group (n = 86)

	Group, No. (%)	
	Standard care (SC) (n = 43)	SC + robot distraction (n = 43)
Age, median (IQR), years	9 (7, 10)	9 (7, 10)
Sex (Male)	26 (60.5)	21 (48.8)
Ethnic minority	9 (22.5)	10 (23.8)
Heart rate (beats/min), median (IQR)	102 (83, 118)	108 (89, 124)
Parental Report of Prematurity	6 (15.0)	1 (2.4)
Previous ED visit	31 (77.5)	36 (85.7)
Previous hospitalization	10 (25.0)	15 (35.7)
Previous IV placement or blood draw	29 (72.5)	35 (83.3)
Parent-asserted distress during prior IV placements/blood draw		
1 (no distress)	6 (20.7)	8 (22.9)
2	4 (13.8)	5 (14.3)
3	8 (27.6)	4 (11.4)
4	8 (27.6)	11 (31.4)
5 (as distressed as possible)	3 (10.3)	7 (20.0)
Parent-asserted distress during other medical procedures		
1 (no distress)	9 (22.5)	8 (19.1)
2	5 (12.5)	9 (21.4)
3	13 (32.5)	5 (11.9)
4	11 (27.5)	12 (28.6)
5 (as distressed as possible)	2 (5.0)	8 (19.1)
Use of topical analgesia	42 (100)	36 (92.3)
Successful first IV attempt	33 (78.6)	29 (74.4)
Discharge diagnosis	(n = 39)	(n = 42)
Abdominal disease	19 (48.7)	17 (40.5)
Neurologic diagnoses	7 (17.9)	7 (16.7)
Infectious disease processes	5 (12.8)	6 (14.3)
Limb fracture	3 (7.7)	6 (14.3)
Viral Illness/fever	3 (7.7)	2 (4.8)
Respiratory disease	1 (2.6)	2 (4.8)
Other Diagnoses	1 (2.6)	2 (4.8)

ED emergency department, *IQR* interquartile range, *IV* intravenous

to the study. Median age was 9 years (IQR 7,10) (Fig. 3, Table 1, Appendix 1 in ESM).

The median years of clinical nursing experience was 5 (IQR 3,8). 96% (79/82) of children reported enjoying playing with electronic devices and 53% (42/79) reported use of electronic devices daily.

Child distress

Total OSBD-R score (mean score ± SD) in the robot group was 0.78 ± 1.32 compared to 1.49 ± 2.36 in the standard care group ($p < 0.05$). Distress during IV insertion in the robot group was 0.37 ± 0.74 compared to 0.74 ± 1.19 in the standard care group ($p = 0.03$) (Table 2).

Child pain

Median child-reported FPS-R scores during IV insertion for the standard care group was 4 (IQR 2,6) compared to 2 (IQR 0,4) in the robot distraction group ($p = 0.13$) (Table 2). Regression analyses demonstrated that age, sex, ethnicity, prematurity, previous ED visit, previous hospitalization and history of a previous poke had no significant evidence of effect on changes in self-reported pain scores (Appendix 2 in ESM). In a post hoc subgroup analysis of children who received topical anesthesia, there was still no statistically significant difference in pain reduction.

Parental anxiety and satisfaction

Pre-procedural parental anxiety was comparable between groups, with mean scores of 37.7 ± 11.5 (robot) and 39.8 ± 12.8 (standard care) ($p = 0.47$). Parents reported moderate levels of anxiety immediately after IV insertion, with mean STAI-S scores of 31.3 ± 8.5 (robot) and 36.7 ± 11.9 (standard care) ($p = 0.04$).

Ninety-three percent (39/42) of parents were very satisfied with the IV insertion in the robot group compared to 74% (29/41) in the standard care group ($p = 0.03$). 95% (40/42) of parents were very satisfied with their child's pain management in the robot group compared to 72% (28/39) in the standard care group ($p = 0.002$). When asked whether they would use the same pain management methods for their children in the future, 100% (42/42) of parents in the robot group reported 'yes' versus 95% (37/39) for standard care ($p = 0.23$). Seventy-eight percent (32/41) of nurses were very satisfied with the IV insertion in the robot group compared to 69% (27/39) in the standard care group ($p = 0.39$). When asked whether they would use similar methods to manage pain for future IV insertion, 100% (41/41) in the robot group reported they would use it again, versus 92% (36/39) for standard care. Mean heart rate during the procedure did not significantly differ between the robot (120 ± 27) and standard care (119 ± 24) arms ($p = 0.86$).

Regression analyses

Robotic intervention was found to significantly reduce total distress after adjusting for age, sex and history of a previous poke (0.94 [95%CI: 0.14, 1.74]). Children *without* prior needle procedures had greater procedure-related increases in distress (− 0.58 [95%CI: − 0.99, − 0.18]). Female sex of the child was associated with greater parental anxiety (2.78 [95%CI: 0.34, 5.21]) during the IV insertion (Appendix 2).

Table 2 Observed distress and self-reported pain scores (n = 81)

	Group		p value*
	Standard care (SC) (n = 39)	SC + robot distraction (n = 42)	
Weighted Phase 1 OSBD-R score (pre-procedure) mean (SD)	0.40 (1.04)	0.27 (0.68)	0.24
Weighted Phase 1 OSBD-R score (pre-procedure) median (IQR)	0 (0, 1.00)	0 (0, 0.21)	
Weighted Phase 2 OSBD-R score (during procedure) median (IQR)	0.74 (1.19)	0.37 (0.74)	**0.03**
Weighted Phase 2 OSBD-R score (during procedure) median (IQR)	0.24 (0, 1.00)	0 (0, 0.30)	
Weighted Phase 3 OSBD-R score (post-procedure) mean (SD)	0.35 (0.76)	0.13 (0.32)	0.11
Weighted Phase 2 OSBD-R score (post-procedure) median (IQR)	0 (0, 0.28)	0 (0, 0)	
Total distress OSBD-R Score mean (SD)	1.49 (2.36)	0.78 (1.32)	**0.047**
Total distress OSBD-R Score median (IQR)	0.58 (0.09, 1.97)	0.22 (0, 0.88)	
Phase 2 score—Phase 1 OSBD-R score mean (SD)	0.34 (0.73)	0.10 (0.86)	0.057
FPS-R Score (pre-procedure), median (IQR)	3 (2, 6)	2 (0, 6)	0.37
FPS-R Score (during procedure), median (IQR)	4 (2,6)	2 (0, 4)	0.10
FPS-R Score change (during procedure minus pre-procedure), median (IQR)	0 (− 2, 2)	0 (-2, 0)	0.55

Bold indicates statistically significant values ($p < 0.05$)

OSBD-R Observed Scale of Behavioural Distress- Revised, *FPS-R* Faces Pain Scale-Revised, *IQR* interquartile range, *SD* standard deviation

*Calculated utilizing the Mann–Whitney test

Technical difficulties

Technical difficulties in the robot-based distraction arm were noted in 60% (26/43) of cases. Difficulties were split into five main categories: connectivity (16/26); robot delaying IV start (3/26); unresponsive/frozen tablet (2/26); volume control (2/26) and unexpected robot fall/shut down (3/26).

Discussion

Interpretation of findings

Our trial has demonstrated a modest decrease in overall behavioral distress with the addition of robot distraction to standard care, but not pain. Parents in the robot group reported lower anxiety immediately after the procedure and higher satisfaction with IV insertion and their child's pain management. Of note, no differences in heart rate were found between groups, consistent with prior evidence that heart rate as a proxy for distress and pain in this age group is unreliable [18, 19].

Comparisons to previous studies

A recent systematic review of over 100 digital technology trials (mainly watching a show and virtual reality) for acute procedural pain has shown a modest but clinically important reduction in both pain and distress [7]. Limited previous studies specifically using robotic distraction have also yielded similar results to our study. A trial of 40 oncology patients aged 4–9 years assessed active versus passive distraction using robotic technology when undergoing subcutaneous port needle insertions [20]. The study found that distress was reduced more in the active distraction arm (robot dancing/singing) but there was no difference in pain. Another trial of 57 children aged 4–9 years tested robot-based distraction for vaccinations; interactions with the robot significantly reduced distress and pain [21].

Our study demonstrated that younger age, female sex and no prior history of a needle poke were related to increased total observed distress. The influence of age has been extensively studied and our findings are consistent with current literature [22–25]. Younger children may lack calming self-regulation skills for medical procedures and therefore display higher levels of distress. Noted sex differences are also consistent with previous studies that demonstrate girls tend to display more clinging and crying behaviors and are more dependent on support seeking behaviors during stressful situations [26, 27]. In contrast, previous exposure to a needle-related procedure may have reduced observed distress because children were familiar with the environment and could anticipate what to expect [28].

Even with a dedicated research assistant, technical difficulties occurred in 60% of encounters, possibly leading to under-estimation of effect size in our trial. A previous RCT using similar robotic technology noted technical difficulties in 35% of encounters [20]. Solutions may include upgrades to operating software, changes to programming, and troubleshooting education for handlers. Finally, low pain scores seen in both study arms are likely due to the known effectiveness of topical anesthetics [29, 30].

Limitations

As five children who were randomized ultimately did not receive an IV catheter, they could not be included in analyses. Due to the need to collect self-reported pain and distress, children with neuro-cognitive delays and hearing/visual impairments could not be included, limiting the generalizability of our results to these groups. Further, standard care was not 'standardized', as each parent-nurse team personalized their approach to each child, as would happen in the clinical setting. Given the nature of the intervention, it was not possible to blind participants, research staff or nurses. Topical anesthetic use was not controlled, as it is not always offered and used in the real-world emergency setting. The robot performed the same standardized actions for all participants with no adjustment for individual preferences. If actions performed were unappealing to patients, it may have reduced effectiveness of the intervention. Finally, the costs of the MEDi™ robot (currently $20,000) are higher than other technology-based distractions and will limit generalizability to lower resource settings.

Clinical implications

Use of a humanoid robot for distraction during brief medical procedures may be of use in higher resource settings, as it positively impacts both child distress and parental anxiety. Despite technical challenges, the majority of families and healthcare providers still wished to use it.

Research implications

Further trials on the effect of humanoid robot-based distraction could be completed for different medical procedures in various clinical settings. There is also potential to compare other methods of distraction (i.e. virtual reality, non-technology distraction) to robot-based therapy. Efforts to decrease the frequency of technical difficulties would likely improve utility of the robot.

Conclusion

Humanoid robot-based distraction therapy is associated with a modest positive impact on child distress for pediatric IV insertion, but not pain. It can be considered a potential tool in the ED toolkit for procedural pain-associated distress reduction.

Acknowledgements This study was funded through a Support Platforms for Integrated Research (SPIR) Grant from the Women & Children's Health Research Institute (WCHRI, Edmonton, Alberta, Canada), for which Dr. Samina Ali and Dr. Sarah Curtis are co-principal investigators (2014–2018). Dr. Hartling is supported by a Canada Research Chair in Knowledge Synthesis and Translation, and is a Distinguished Researcher with the Stollery Science Lab. Dr. Scott is supported by a Canada Research Chair in Knowledge Translation in Child Health, and is a Distinguished Researcher with the Stollery Science Lab.

Funding Dr. Tanya Beran is the founder of RxRobots, a company that is the maker of the robot's software used in this study. Our team purchased the robot at full price, with a Stollery Children's Hospital Foundation Grant. Dr. Tanya Beran has not participated in data collection or statistical analysis.

Compliance with ethical standards

Conflict of interest Dr. Tanya Beran is the founder of RxRobots, a company that is the maker of the robot's software used in this study. Dr. Tanya Beran has not participated in data collection or statistical analysis.

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