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ACTA PÆDIATRICA NURTURING THE CHILD WILEY

BRIEF REPORT

Randomising children to electronic distraction and vibration was not associated with reduced pain during childhood vaccinations

Vaccines are major medical advances, but they are also the most common cause of iatrogenic childhood pain.[1] Controlling pain during vaccinations is vital, as it encourages families to follow immunisation schedules properly.[2] Several interventions have been used to reduce childhood pain and alleviate distress during procedures involving needles.[2] We assessed whether electronic distraction and vibration reduced crying duration during vaccinations and examined parental perceptions of any pain and anxiety experienced by their children.

This randomised clinical trial was approved by Ethics Committee of La Salle University, Brazil, and registered as a clinical trial (NCT 03540589).

Children were evaluated during routine vaccination appointments and included if they were one to three years of age and only receiving a single vaccination. They were excluded if the parents refused to take part, they had waited more than 40 minutes or had previously been included in the study. The waiting time criterion was to avoid clinic delays. The research was carried out at the vaccine centre of the Hospital Moinhos de Vento, Porto Alegre, Brazil, and the 204 participants were randomised to four groups with opaque envelopes produced using computer randomisation. The sample size was calculated based on a power of 80%, an alpha error of 5%, and a mean crying duration of 30.0 ± 15.0 seconds in the electronic distraction plus vibration group and 40.0 ± 20.0 seconds in the control group. This gave us an effect size of 0.56 and a sample size of 204 patients. Group one (n = 56) watched a video chosen by their parents from an age-appropriate selection on a computer tablet. Group two (n = 50) were given a reusable Buzzy vibration device (MMJ Labs, Atlanta, GA) that was placed about 4 cm above the injection site by a professional 15-45 minutes before the procedure to decrease pain. The third group (n = 51) received both interventions simultaneously. Although the fourth group were the controls, their parents were allowed to distract them with electronic devices and 30% chose to do this. All the children received standard care of lidocaine and prilocaine plus nutritive sucking or breastfeeding. The majority (83%) were accompanied by their mother, and the father or another adult was present in 34% and 8% of cases, respectively.

The main outcome was crying duration, which was recorded for 120 seconds after the injection. The recorded audio was then evaluated by an investigator who was blinded to the randomisation. The second outcome was the parents' perceptions of the children's responses to the vaccination, which were measured by three

TABLE 1 Demographic and clinical characteristics of the 204 study subjects

	Electronic distraction (n = 56)	Vibration (n = 50)	Electronic distraction plus vibration (n = 51)	Control group (n = 47)	*P*
Age, months, median (IQR)	22.0 (19.0-35.5)	23.5 (18.0-35.5)	21.0 (18.0-31.0)	26.0 (20.0-31.0)	.80
Sex, male, n (%)	16 (28.6)	24 (48.0)	20 (39.2)	18 (38.3)	.24
Premature, n (%)	5 (8.9)	7 (14.0)	2 (3.9)	6 (12.8)	.32
Previous hospitalisation, n (%)	9 (16.1)	14 (28.0)	2 (3.9)	10 (21.3)	.01
Anaesthetic, n (%)	8 (14.3)	8 (16.0)	8 (15.7)	7 (14.9)	.99
Sucking, n (%)	12 (21.4)	10 (20.0)	14 (27.5)	10 (21.3)	.81
Ice, n (%)	0	1 (2.0)	0	1 (2.1)	.53
Breastfeeding, n (%)	0	1 (2.0)	0	2 (4.3)	.24
Electronic distraction, n (%)	56 (100)	11 (22.0)	51 (100)	14 (29.8)	<.001
Crying duration, seconds, median (IQR)	19.6 (11.6-35.3)	21.9 (14.6-30.5)	18.0 (10.9-27.9)	24.4 (12.7-32.6)	.43

Abbreviation: IQR, interquartile range.

yes or no questions based on Luthy et al[3] The parents were asked whether the current vaccination experience was better than the last one and whether they thought their child had experienced distress and pain.

We used the chi-square test and Fisher's exact test to evaluate categorical variables and ANOVA or the Kruskal-Wallis test to evaluate continuous variables. Variables with a $P < .1$ in the univariate analysis for the occurrence of the outcomes were included for adjustment in the linear regression model using forward regression.

During the study period of May 21 to October 30, 2018, 8514 individuals were vaccinated at centre and 7492 did not meet the inclusion criteria. After the exclusion criteria were applied, there were 220 children, but 16 were excluded after randomisation due to data recording issues (Figure S1). The patient characteristics and results are described in Table 1.

The overall median and range for crying duration was 21.0 (interquartile range 12.8-30.6) seconds with no differences between the study groups. When the multivariate analysis was adjusted for the study group and prematurity, a history of prior hospitalisation maintained an independent association with a longer crying duration, with an unadjusted beta coefficient of 7.7 ($P = .03$). This may have been linked to more invasive procedures among previously hospitalised premature children.

More parents in the electronic distraction plus vibration group said it was better than their last vaccination experience than control parents (72.5% versus 46.8%, $P = .04$). Electronic distraction was associated with reduced distress compared to the controls (69.6% versus 38.3%; $P = .004$). There was no difference in pain perception between the groups.

A meta-analysis was published in 2020 that evaluated the efficacy of digital distraction and showed modest pain and distress reductions in children undergoing painful procedures.[4] It also found that parental perceptions of distraction were less frequently explored and inconclusive. However, studies have disagreed. For example, Luthy et al found no evidence that distraction reduced perceived pain or distress,[3] while Shahid et al showed that they did.[5]

Electronic distractions and vibrations were not associated with reduced pain in children undergoing vaccinations, but parents thought that electronic distractions reduced their children's distress and combining both interventions were an improvement on previous experiences. The study highlighted that pain relief measures were particularly important after prior hospitalisation. These are important results, because parental perceptions are a key factor in timely vaccinations.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.