Videogame playing as distraction technique in course of venipuncture

Giocare con i videogiochi come distrazione attiva in corso di venipuntura

M. Minute,1 L. Badina,1 G. Cont,1 M. Montico,2 L. Ronfani,2 E. Barbi,3 A. Ventura1

Abstract

Background: Needle-related procedures (venipuncture, intravenous cannulation) are the most common source of pain and distress for children. Reducing needle related pain and anxiety could be important in order to prevent further distress, especially for children needing multiple hospital admissions. The aim of the present open randomized controlled trial was to investigate the efficacy of adding an active distraction strategy (videogame) to EMLA premedication in needle-related pain in children.

Methods: One-hundred and nine children (4 - 10 years of age) were prospectively recruited to enter in the study. Ninety-seven were randomized in two groups: CC group (conventional care: EMLA only) as control group and AD group (active distraction: EMLA plus videogame) as intervention group. Outcome measures were: self-reported pain by mean of FPS-R scale (main study outcome), observer-reported pain by FLACC scale, number of attempts for successful procedure.

Results: In both groups FPS-R median rate was 0 (interquartile range: 0-2), with significant pain (FPS-R>4) reported by 9% of getti. La mediana per quel che riguarda la scala FLACC è stata pari a 1 in entrambi i gruppi, mentre la percentuale di bambini con dolore grave (FLACC>4) è stata del 18% nel gruppo di controllo e del 9% in quello sperimentale; tale differenza non è statisticamente significativa (p=0.2). La mediana dei tentativi necessari è stata pari a 1 in entrambi i gruppi, con un range interquartile compreso tra 1 e 2. La distrazione attiva è stata applicata con facilità ed accettata molto bene sia dai bambini sia dagli operatori.

Conclusioni: La distrazione attiva non migliora l’analgesia già fornita con EMLA per quel che riguarda le procedure di venipuntura ed incannulamento venoso, ciò nonostante è risultata essere facilmente applicabile e apprezzata dai bambini. Potrebbe essere utile indagare questa tecnica di distrazione in corso di altre procedure dolorose.
subjects. FLACC median rate was 1 in both groups (interquartile range 0-3 in CC group; 0-2 in AD group). The percentage of children with major pain (FLACC>4) was 18% in CC group and 9% in AD group (p=0.2). The median of necessary attempts to succeed in the procedures was 1 (interquartile range 1-2) in both groups.

Conclusion: Active distraction doesn’t improve EMLA analgesia for IV cannulation and venipuncture. even though, it resulted in an easily applicable strategy appreciated by children. this technique could be usefully investigated in other painful procedures.

Introduction

Needle-related procedures such as venipuncture or intravenous cannulation are commonly performed both on healthy (routine blood sampling) and ill (in- and outpatients) children. They are, therefore, one of the most common sources of pain and distress for children: the pain due to these procedures is rated from moderate to severe in 36% of children 3 to 6 years of age and in 13% of children 7 to 17 years of age; pain, including the mild one, was described in more than 50% of patients in both population.

Unmanaged pain and distress may have clinical implications on children, such as acute vasovagal responses, change in heart rate and stress hormone levels, chronic needle phobia and avoidance of health care. Therefore the necessity of pain management is now consolidated: the approach can be both pharmacological and non pharmacological and often these approaches are integrated.

Non pharmacological approach is based on different techniques such as preparation programs, correct positioning and both passive (movies, toys, music, bubble bowling etc) and active distraction. Distraction is described as “a class of cognitive strategies that divert attention from a noxious stimulus through passively redirecting the subject’s attention or by actively involving the subject in the performance of a distracter task”. Distraction affects the perception of pain both indirectly (attention capabilities are finite and distraction can consume some of them, leaving less focus available to perceive pain) and directly (distraction interferes with neuronal activity associated with pain which is modulated by a gating mechanism influenced by cognitive processes).

While passive distraction’s techniques have been investigated in many studies, that show that this kind of pain management interferes with pain perception thus modifying the quality of pain itself, active distraction’s effectiveness is not well defined.

The aim of this study was to investigate the efficacy of an active distraction strategy (video-game playing) compared to our standard procedure (topical anesthetic cream) in children 4 to 10 years of age.

Materials and methods

Study Design:
The study was an open randomized controlled clinical trial. It was designed to test the effectiveness of active distraction with a videogame on procedural pain due to IV cannulation and venipuncture. The study took place in a Pediatric Third Level teaching hospital, at IRCCS “Burlo Garofolo”, Trieste, in the Pediatric Clinic, Gastroenterology Service and Day Hospital of the Institute, where children were recruited.

The study was initiated and designed exclusively by the investigators and its protocol was approved by the Independent Bioethical Committee of the Institute. Parents of all children provided written informed consent.

The videogame console (Nintendo “) and the video-game CD Wii Play were donated by an association of volunteers offering time to hospitalized children. The researchers had all the responsibility in the design of the study, the collection and the analysis of the data, the presentation of the manuscript and the decision to submit the manuscript to publication.

Patients:
From April to December 2009 we offered study entry to all children 4 to 10 years of age, who needed to undergo IV cannulation and venipuncture. Exclusion criteria were: positive history for epilepsy; known hypersensitivity to amide anesthetics; impossibility for the personnel to execute the procedure on the hand or on the elbow; impossibility for the child to cooperate and play with the videogame.

Once eligible children were identified, parents were both provided a pamphlet and orally instructed about the study and the proce-
dures to let them decide whether they wanted their child to enter the study and to sign the informed consent. After that, children enrolled were randomly assigned to control or experimental group. Randomization procedure was managed by an independent statistician at the Epidemiology and Biostatistics Unit of the Institute using a computer program. Randomization list was generated in blocks of 10. The allocation concealment was guaranteed through the use of closed opaque envelopes, numbered consecutively. In each envelope the assignment group was indicated, based on randomization. Medical personnel directly involved in the management of the patient opened the lowest numbered envelope available and assigned the patient to the correspondent group.

**Procedure:**

Pediatric nurses premedicated children by applying EMLA\textsuperscript{18,19} cream, on both the dorsum of the hands and the antecubital fossas; the cream was maintained on the skin at least 60 minutes, by mean of an occlusive dressing. After 60 minutes or more, the children and their parents were invited to the medication room, where nurses removed the dressing and the cream and explored the application sites to find the best vein to be cannulated. The procedure was explained step by step to children and parents. All the procedures were routinely performed with the parent seated and the child seated on parent’s legs, unless the child chose to sit by his own to be more comfortable. The child’s arm was leaned on the operating bed.

For children in the control group the procedure was at this point performed with no further device. Children assigned to experimental group, on the other hand, were shown at this point the distraction device: it consisted on a simple videogame, *Wii-Play*\textsuperscript{®}, rated 3+, in which the child had to aim to different targets using a single-handed remote as a pointer. In order not to false study’s results, all children played the same game and we didn’t allow them to familiarize earlier with the game since this would have not been adherent to hospital’s routine reality. The console was at least 1 meter away from procedural site, in order not to interfere with nurse’s work, and the remote, wrapped in a rubbery shell, was secured with a lace to the child’s wrist on the side where the procedure wasn’t being attempted. The children were instructed to aim a target and to try to concentrate on the video in front of them. They were allowed both to play more than a match if the procedure required more than one attempt and to finish the match when the procedure was faster.

**Data Collection:**

While the children underwent the procedure, an observer filled in the form with personal (date of birth, sex) and procedural data (kind and site of procedure, number of attempts to perform a successful procedure).

Primary outcome of the study was self-report level of pain evaluated with Faces Pain Scale Revised (FPS-R)\textsuperscript{20,21} When the procedure was over, the child evaluated the pain by choosing on the FPS-R\textsuperscript{20,21} between six faces that represented different levels of pain, from no pain to the worst pain ever. The rate was then translated into numbers from 0 to 10, with 2, 4, 6 and 8 as intermediate scores. (Fig 2)

Secondary outcomes were: 1) the children’s reaction to pain evaluated when the procedure was over by the observer through the FLACC behavioral scale and 2) the number of attempts needed to perform a successful procedure. The FLACC tool assesses changes in five categories of behavior (namely: Face, Legs, Activity, Crying and Consolability), rating each one on a scale of 0–2 (Table 1). Ten is the maximum score indicating severe pain and a score <2 generally indicates absence of pain\textsuperscript{22,23}. A FLACC score higher than 4 is considered as indicator of moderate pain\textsuperscript{24}.

**Statistical Analysis:**

Based on available literature\textsuperscript{25, 26} we assumed a mean FPS_R score of 2.5 (standard deviation=1.8) in the EMLA control group. We estimated a priori that the enrollment of 100 children would provide the study with a statistical power of 80% to detect a 1 point reduction from this assumed mean pain score in children allocated to EMLA + distraction device, given a two-sided type 1 error of 0.05.

![Figure 2](https://example.com/Figure2.png)
Categorical data are presented as numbers and percentages and continuous data as medians and interquartile-ranges, as data explored visually and with the Kolmogorov Smirnov test, showed a non-normal distribution. Continuous data concerning study outcomes were presented also as means and standard deviations which were more informative than medians and interquartile-ranges.

Baseline characteristics of the two groups were compared with the chi-square test for proportions and with the Mann-Whitney non-parametric test for continuous data. Differences in clinical outcomes between the two study groups were analyzed for categorical outcomes using the chi-square test; for continuous outcomes using the Mann-Whitney non-parametric test.

Two regression logistic analysis were carried out to explore the relationship between a dichotomous variable of pain (presence of clinically significant pain in FPS-R scale and in FLACC scale if score >4) and type of intervention taking into account possible unbalancing between intervention groups.

The data were analyzed using SPSS for Windows 11.0 (SPSS 2001) according to the intention-to-treat principle. All p values will be two-sided, with a p value of less than 0.05 used to indicate statistical significance.

Results

Demographic characteristics

From April to December 2009, according to inclusion and exclusion criteria, 109 eligible children and their parents were approached about the study; 107 agreed to enter the study but only 97 were enrolled, since 4 children didn’t use EMLA and 6 didn’t complete the consent form in its totality.

After parents' written informed consent was obtained, 50 (51.5%) participants were randomized to the conventional care group (CC) and 47 (48.5%) were randomized to the intervention group (active distraction, AD). (see Fig 1) After randomization, in CC group 1 subject received AD and 1 midazolam before evaluation; in the AD group, 2 subjects needed physical restriction and consequently stopped playing the game. However, the analyses were carried out according to the intention-to-treat principle.

Main characteristics of the enrolled population and of the procedures are reported in table 2. The median age for both groups was 7 years. Forty-nine males and 48 females were randomized: in CC were allocated 19 (38%) males, while in AD 30 (64%) males. This casual unbalance between genders was statistically significant (p=0.01).

The number of procedures, which children had previously undergone, was extremely variable, with some children at their first experience and others who had undergone more than fifty procedures. In CC group the median was 6 (interquartile range 3-15), while in the AD group the median was 5 (interquartile range 2-15).

Forty-three venipunctures and 54 IV cannulations were performed. At first attempt, each procedure was performed optionally on hands or elbows (Tab. 2). The unbalance between the two procedures in AD group was not statistically significant.
All randomized subjects maintained EMLA on the site of the first two procedures for more than 60 minutes, but three of those subjects who needed more than two attempts (1 in CC group and 2 in AD group) didn’t have EMLA on the site of the successful procedure. (Tab. 2)

Outcomes:
No differences in self-report level of pain evaluated with FPS-R scale were found: results showed in both groups a median score of 0 (interquartile range: 0-2, and a mean score of 1.36 (Sd 2.5) in CC group vs 1.5 (Sd 2.5) in Ad group. Significant pain (FPS-R>4) occurred in 4 (8%) subjects in CC group and in 4 (9%) subjects in Ad group. (Fig 3)

According to the observer’s evaluation, rated with FLACC Behavioral Pain Assessment, no statistically significant differences were found: the median score was 1 in both groups (interquartile range: 0-3 in CC group; 0-2 in AD group) and the mean score was 2.1 (SD 2.7) in CC group vs 1.5 (SD 2.3) in AD group. Significant pain (FLACC>4) occurred in 9 (18%) children in CC group and in 4 (9%) children in AD group. This difference wasn’t statistically significant (p=0.2). (Fig 4)

Considering the attempts that were necessary to perform a successful procedure, data showed that 36 (72%) procedures in CC group and 33 (72%) procedures in AD group were successful at first attempt. The median of necessary attempts is 1 in both groups (interquartile range: 1-2). (Fig 5)

In order to evaluate if the unbalances between the two groups for sex and type of procedure could have influenced the main outcomes of the study (FPS-R and FLACC scales), univariate analysis was carried out to evaluate differences in pain between male vs female and between venipuncture and cannulation. These analysis didn’t show any statistically significant difference.

No child refused to play and more than 70% asked to play further well after the end of the procedures. Nurses appreciated this technique too and the caregivers of the Day Hospital Unit asked for hardware and software to go on with the active distraction even after the conclusion of study period.

Discussion

Pain consists of two different elements, nociception and suffering. The latter is linked with emotional and cognitive aspects. Therefore adding a distraction technique to standard care of procedural pain may rationally improve pain control. This endpoint is important for routine procedures such as venipuncture and IV cannulation, particularly for chronically ill children, since it is very likely that they will experience such procedures repeatedly in their lifetime. It is well known that previous experience can shape future pain perception and that patients don’t get used to pain27.

In the literature there are many studies that evaluated the efficacy of distraction in reducing procedural pain, as shown in Kleiber and Harper’s metanalysis10. However, we could not find exhaustive studies that investigated venous accesses, EMLA premedication and active distraction at the same time. Only the study by Windich-Biermeier et al. approached these three items, using both active (soap bubbles, Game Boy®, interactive books) and passive (audio-
books, Virtual Reality Glasses) distracters. These authors stated that distraction itself is efficient in reducing pain, but they weren’t able to rate single distracters’ efficacy. Our data show that there is no difference in self-reported pain when adding a videogame distraction technique to EMLA cream. This could be because of the high efficacy of topical anesthesia in this setting. Considering that “severe pain” is defined for FPS rates >4, it is evident that standard analgesia’s efficacy is equal to 90% in the control group, making very difficult to increase its efficacy by adding active distraction. We might suppose that this depended on EMLA’s efficacy but this conclusion should have been validated by adding a third group of randomization, in which children who played with the videogame wouldn’t have been premedicated with EMLA cream.

According to FLACC scale, the observer’s evaluation based on behavioral parameters that are influenced not only by biochemical but also by emotional factors, there isn’t evidence of a difference between the two groups as well. None-the-less it is interesting to notice that in the control group there are twice as many subjects with significant distress (FLACC>4) as in the intervention group: 18% versus 9%. Even if this difference isn’t statistically significant (p=0.2), it shows a decreasing trend that is possibly connected with the affective-cognitive aspect of pain. This issue could be addressed in a wider population and in the setting of a more painful procedure.

We need to underline the fact that the pain scores we obtained were very low, lower than other studies and therefore lower than expected, especially given the youth of the patients involved. This result may depend on the expertise of the folks doing the procedures and it should be further evaluated.

A further analyzed outcome was the number of attempts necessary to perform a successful procedure: also according to this parameter there was not a statistically significant difference. In both groups 70% procedures were successfully performed at first attempt and 90% at second. These data shows that an active distraction with videogames is applicable during venipuncture or IV cannulation, since it doesn’t interfere with the procedures, not increasing the number of attempts. This result may be relevant for studies in different settings, such as other painful procedures (e.g. suturing in the emergency room).

This study presents some limitations. First, it wasn’t possible to blind the evaluators. Since the intervention was whether children play with the videogame or not, the patients and their parents were aware of the group they belong to and so were the operators. We previously assessed the literature to find out whether there was a pain assessment scale based only on facial observation in order to convey blindness to the study by adding a second observer, who could have given an opinion on a close-up video recording of the patient, but, to the best of our knowledge, we weren’t able to find any scale which fitted the age group we investigated.

Second, randomization generated a casual unbalance between groups that was showed for sex and type of procedure. However, multivariate analysis didn’t show any effect of these variables on study outcomes. Third, this study was designed as superiority trial and the sample size was calculated on the hypothesis that EMLA plus active distraction offered an advantage over EMLA alone, as reported by previous literature. We didn’t confirm this figure, for the reasons described above. Therefore, this study is underpowered to exclude the existence of some differences between the 2 groups. However, given the observed results, it’s unlikely that we missed clinical relevant differences for the study main outcome.

We can conclude that in this experience active distraction did not improve EMLA analgesia for IV cannulation and venipuncture. None the less, active distraction was easily applicable and appreciated by children and staff. This technique could be usefully investigated in other painful procedures; its efficacy may be better evaluated by adding distress or anxiety scores.

References