Reducing Pain Associated with Immunization in Three- to Four-Year-Old Children: A Randomized Clinical Trial

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Abstract

Aim: Few previous studies have examined the effects of the distraction approach by focusing on children under five years of age receiving immunizations. This study was conducted to examine the effects of distraction designed to reduce 3 to 4 year-old children’s pain during immunizations.

Methods: Participants were 102 children aged 3 to 4 years who were given an immunization in an urban pediatric clinic in Japan. They were randomly assigned to one of three groups, which either 1) watched an animated DVD (Animation group: n = 35), 2) received standard medical routine with the usual office routine (Control group: n = 33), or 3) received an interactive intervention using picture cards (Card group: n = 34). Pain measurements at four phases (baseline, during preparation, during injection, and following injection) were made using the Face Legs Activity Cry and Consolability (FLACC) behavioral pain scale. Parents rated their child's anxiety prior to procedure and during the procedure on a Visual Analogue Score (VAS).

Results: There was a significant difference between prior to procedure and during the procedure VAS scores only in the control group (p = 0.021). In the three groups, the FLACC scores increased significantly from baseline to during preparation (Animation group: p = 0.002, Card group and Control group: p < 0.001). However, from during preparation to during injection, the FLACC score of only the Animation group increased significantly (p = 0.001). From during injection to following injection, the FLACC scores in the three groups showed a significant decrease (p < 0.001 in each of the three groups).

Conclusion: Immunizations are painful procedures for children that cause considerable pain and anxiety. Watching cartoons and interactive distraction do not seem to be effective in reducing high levels of pain.

Keywords: Young Child; Pain; Anxiety; Immunization; Distraction; Randomized clinical trial

Introduction

Pain affecting infants and young children induces not only acute changes, but also permanent structural and functional changes [1]. Children feel marked distress when receiving injections during medical treatment. For children, an injection is one of the most dreadful experiences in life [2]. Three- to four-year-old children in particular, who are at a critical stage in emotional development [3], feel markedly uneasy about injections and tend to become frightened of medical procedures. On the other hand, as they are immature in terms of cognitive development, they still largely unable to properly convey their feelings verbally or address problems on their own [4]. Among young children, three- to four-year-olds in particular become markedly distressed when they undergo medical procedures. In order to reduce children's distress, an increasing number of studies have been conducted on psychological interventions for young children undergoing medical procedures [5-11].

One such technique is distraction, a non-pharmacological and psychological form of intervention. This technique aims to draw children's attention away from medical procedures using moving toys or other things to alleviate their pain and distress as much as possible [12]. However, distraction studies that have set narrow parameters for certain variables, such as age, have not been significantly conducted [13]. Also, few previous studies have examined the effects of different kinds of distraction occurring simultaneously by focusing on children under five years of age receiving immunizations.

The purpose of this study was to examine the effects of distraction to alleviate pain felt by three- to four-year-old children at the time of immunization. Pain is an unpleasant sensory and emotional experience (International Association for the Study of Pain 1979) and anxiety is the feeling of being very worried. Young children are immature and often do not have the language or cognitive sophistication to express the difference between their pain and anxiety. In this study, pain thus includes physical pain as well as any unpleasant feeling (anxiety, distress, fear, and so on).

Methods

Participants

The study protocol was approved by the Ethics Committee at the Faculty of Medicine, Kagawa University, Japan. This randomized, controlled study was conducted at a pediatric clinic located in a suburban area of a small city in Japan. Participants were children who visited the clinic for immunization, and who satisfied all of the following inclusion criteria: They were children (1) aged between 3 and 4 years old; (2) with no acute symptoms suggestive of any health problems; and (3) showed no developmental disorder or delay.

Procedure

Participants were recruited by a researcher in the waiting room of the clinic. The parents' informed consent and the children's assent were obtained. The parents completed a demographic questionnaire about their children and rated their children's anxiety before procedure on VAS (prior to procedure). In the examining room, the parents held and sat with their children during the procedure. The researchers assigned patients to three types of intervention in the order of their arrival based on the randomization table that was made by an assistant. After the physician examined the child one of three interventions was offered to each child during the procedure. The usual routine followed by a nurse in the clinic consisted of their offering encouragement and compliments (the control group). In addition, two types of intervention were implemented for children in the distraction intervention group by the researcher: children...
either watched an animated DVD (the animation group), or guessed the names of characters drawn on cards while interacting with the researcher (the card group).

The study was conducted under the following conditions to reduce as much as possible differences in the levels of pain and stimulation caused by injections [7,11,13]: 1) Injections were administered by one physician; 2) Only inactivated vaccines were used; 3) A single dose of 0.5 ml was administered to all patients; 4) The site of injection was the extensor surface of the upper arm; and 5) Only 27G short bevel needles were used. Children’s previous experiences with injection also impact their pain and anxiety. Therefore, children who had undergone a medical procedure involving a needle within 14 days were excluded.

The immunization procedure was as follows: a physician conducted a diagnosis, disinfected the site of injection, and administered an injection while a nurse held the arm of the child. After injection the parents rated the children’s anxiety during procedure using VAS (during procedure) in the waiting room.

**Instruments**

Data were collected using a demographic questionnaire, Visual Analog Scale (VAS), and the Faces Legs Activity Cry Consolability Pain Assessment Tool (FLACC). The VAS consists of a 100-mm horizontal bar with the two end points labeled “no anxiety or fear” and “worst possible anxiety of fear.” It is a scale with a high inter-rater reliability coefficient and concurrent validity, effectively expresses anxiety and is often used by parents and health professionals for alternative assessment [14]. In the present study, parents assessed anxiety of their children both prior to and during the procedure because they understood how their children behaved in normal situations and were able to properly assess anxiety felt by children.

The FLACC, a well-established scale for the assessment of pain caused by short medical procedures, and also with a high reliability and validity [14,15], consists of five behavioral categories (face, leg movement, activities, crying, and cradling). The total score was between 0 and 10 points. The medical procedure was divided into four phases: 1) baseline, in which a physician conducts a physical exam; 2) during preparation, in which a patient’s arm is disinfected and held by a health professional, 3) during injection, in which the needle is inserted to inject a vaccine, and 4) following injection, in which the needle is removed and tape is applied to protect the skin. FLACC tests were conducted for up to 30 seconds. The following two measures were implemented to improve the accuracy and precision of FLACC measurements:

**Retroactive assessment based on recorded images:** As it was necessary to closely observe the children’s behaviors associated with pain over a period of time to determine scores, the children were filmed with a digital high-definition video camera from their entry into the examining room to the completion of procedure.

**Training of raters and sharing of viewpoints for assessment:** Three raters, the researcher and two collaborators, first discussed viewpoints required to determine scores in the present study in order to comprehend and share them. Following this, the raters assessed recorded videos of ten cases. The raters discussed differences in their scoring and problems in determining scores for specific videos, and underwent assessment training three times to improve their accuracy.

Each video recording was rated by two raters (the main rater and sub rater). Within one week following the intervention, the two raters separately watched the video recording and rated the child’s pain using the FLACC scale. If the difference between the raters’ scores was 3 or less, we used the main rater’s score. If the difference was more than 3, the raters watched the video again and reassessed and discussed the video, and then a final decision was made on the score.

**Data analysis**

Qualitative data on the attributes of the participants were compared among the three groups, using the chi-square test. Numerical data, which had not been normally distributed, were compared among the three groups using the Kruskal-Wallis rank sum test. VAS and FLACC scores were compared among the three groups. Score changes over time in different phases were also compared in each group. The normality of results was assessed; normally distributed data were examined using one-way analysis of variance, and other data were compared among the three groups using the Kruskal-Wallis rank sum test. Bonferroni multiple comparisons were also conducted. To examine and compare score differences in each group, matched-pair t- and Wilcoxon signed-rank tests were conducted for normally distributed and other data, respectively. Statistical analysis was performed using IBM SPSS Statistics 20 (Japan IBM, Tokyo, Japan), and the significance level was set at 0.05.

**Results**

During the period of data collection, 111 participants fulfilled the inclusion criteria, and 109 pairs of parents and children agreed to participate in the study. They were randomly assigned to three groups. The final analyses involved a total of 102 pairs (35 in animation, 34 in card, and 33 in control groups) (Figure 1).

Comparisons of attributes of the three groups (gender, age and number of days from most recent medical procedure involving a needle) revealed no significant differences.

**VAS scores**

The mean prior to procedure score received by the three groups was 41.2 ± 36.6 points. There were no significant differences in prior to procedure and during procedure scores between the three groups. There were significant increases between prior to procedure and during procedure scores received only by those in the control group (p = 0.021) (Figure 2).

**FLACC scores**

There were no significant differences in baseline, during preparation, during injection, and following injection scores between the three groups. There were significant increases between baseline and during preparation scores in all three groups (p = 0.002 for the animation group, p < 0.001 for the card and control groups), whereas a significant increase (p = 0.001) was noted between during preparation and during injection scores only in the animation group. There were significant decreases between during injection and following injection scores in all three groups (p < 0.001) (Figure 3).

**Discussion**

The VAS responses were obtained from parents. The score suggested that most of these 3- to 4-year-old children had felt a certain form of pain, such as anticipatory anxiety, even before receiving an immunization. Several previous studies [7,8,16-18] focused on the effects of distraction; in these, parents’ assessments are based on the VAS scale. However no study involving children immediately before receiving an immunization has examined their pain or anxiety as expressed by VAS scores. MacLaren et al. [18] reported that children aged between one and seven years old had...
received a mean score of 60.7 points before undergoing blood sampling. Although the mean scores are lower than those for blood collection, it is inappropriate to compare the present study with research conducted by MacLaren et al., which involved a different type of medical procedure and a different age group of participants.

For all three groups, FLACC scores increased in the *during preparation* phase, compared to the levels *baseline*, reached the maximum levels *during injection*, and decreased *following injection* phases. These results suggest that pain increased in children during preparation, holding their arms while a medical procedure began, or even before they felt physical pain. Pain reached the maximum level when children were stimulated by injection, and it decreased when they were released from the stimulation.

The level of pain felt *during injection* was moderate on the FLACC scale. Since only a short length of time is required to administer an injection for an immunization, these injections may be regarded as less invasive compared to other medical procedures for children diagnosed with a disorder. Nevertheless, these results suggest that pain in children during an immunization is significantly invasive. Children feel pain while an injection is being administered since sedatives are not usually used during immunizations.

![Figure 1: Flowchart of the randomization of subjects and implementation of the study and analyses.](image)

![Figure 2: VAS scores as assessed by their parents](image)

![Figure 3: FLACC scores. FLACC scores in the baseline, during preparation, during injection, and following injection phases were compared between the three groups using the Kruskal-Wallis test. For the three groups, changes in the scores between each phase were compared with the Wilcoxon signed-rank or matched-pairs t-test, depending on the status of the score distribution.](image)
Children's experience of pain can be a factor contributing to an increase in their anxiety. If a physician forcibly administers an injection to a crying child, who is struggling to escape, the child may remember the event associated with a higher level of fear. It is very important to exert efforts to alleviate anxiety and a sense of fear in children undergoing immunizations, even if medical professionals cannot completely eliminate pain due to an injection.

There were no significant differences in VAS scores for anxiety felt by these children in the during procedure phase between the three groups. Anxiety felt by the control group significantly increased between the prior to procedure and during procedure phases, whereas anxiety felt by the animation and card groups, or those who received two types of distraction intervention, did not increase during that period. This suggests that distraction, or an intervention approach implemented for three- or four-year-old children with anxiety undergoing an immunization, may prevent an increase in the level of anxiety associated with the medical procedure.

Pain felt by children in the four phases was assessed using the FLACC scale, and there were no significant differences; distraction intervention did not significantly reduce the level of pain in each phase of the medical procedure. Cohen [16] conducted a study involving children aged three years or younger undergoing immunization using the Modified Behavioral Pain Scale (MBPS), a behavioral scale different from the one adopted in the present study, and the results suggested that there were significant differences in MBPS scores between the during preparation and after injection phases and that distraction intervention alleviated pain. In the present study there were no significant differences in FLACC scores, because the study involved a smaller number of samples compared to that of Cohen's study [16]; the mean age of the children in our study was higher, and the pain in children might have been assessed as being lower than it actually was due to routine services provided for children by physician and nurses in the pediatric clinic. In general, the senses of pain and anxiety significantly vary depending on the individual, and it is difficult for three- or four-year-old infants to accurately describe the anxiety that they felt. Therefore, it is very difficult to understand pain and anxiety in children of this age group.

Regarding score differences for each group, pain felt by the card and control groups significantly increased between the baseline and during preparation phases, whereas pain did not significantly increase between the during preparation and during injection phases. On the other hand, significant two-step increases were noted in pain felt by the animation group between the baseline and during preparation phases, and during preparation and during injection phases. However, considering that there was no significant difference in the score for pain during injection between the three groups, and although children in the animation group notably responded to pain during injection, their pain increase might be inhibited while staff prepared for the medical procedure as compared to the control group. The present study did not determine whether this was attributed to the intervention due to the limitations of analysis.

Although it was not statically significant, the FLACC score of the animation group at baseline and during preparation was lower than that of the other groups. Considering the developmental stage of three- to four-year-old children and that it takes only a few minutes to prepare and administer an injection, animated movies featuring sound and images that attract children's attention by stimulating their eyes and ears, rather than placing emphasis on storylines, should be selected. In developmental psychology, doseness and originality [19] are believed to play a key role in catching children's interest. Animated movies with music selected for the study, very popular with Japanese children, satisfy the doseness criterion. In addition, children experience originality while hearing and viewing unexpected sounds and images. In this sense, animated movies featuring music used in the study were appropriate materials, which attracted the children's interest, stimulating the senses of vision and hearing, and distracted their attention from the medical procedures. Adoption of local anesthetics for decreasing immunization pain has not been employed in Japan. And it is difficult to allow a sufficient amount of time for individual children to prepare themselves when children receive immunizations at clinics. Having young children view popular music-based animated movies is expected to prevent an increase in their level of pain, and this simple distraction approach should be introduced into clinical settings.

As children can enjoy communication with others while remembering something by guessing the names of characters on cards, a game which is appropriate for the developmental stage of three- to four-year-old children, the researchers expected it to reduce their attention to a medical procedure. However, the children's pain continued to increase while staff prepared for the medical procedure. Some previous studies pointed out that it is important for children to choose distraction materials on their own to prepare themselves and have them undergo training in advance, and that an attempt to draw the attention of children with a high level of anxiety may have an adverse effect on them when they are not interested in the distraction materials [17]. Children do not interact with others unless they are strongly interested in the distraction materials. In the present study the children had no choice regarding materials for interaction and there was no time for rehearsal. As a result, the level of interest in the same materials differed from one child to another, and some children were reluctant or hesitant to interact with adults. According to the results of a meta-analysis conducted by Chambers et al., [20] distraction approaches implemented by nurses were more effective than those by parents. Parents are also required to receive training to learn the timing of intervention and other necessary skills. It is desirable to spend a sufficient amount of time to assess the conditions of children and their parents and improve their ability to interact prior to conducting a medical procedure. If interaction-based distraction intervention cannot be provided in such a situation, it may have only limited effects. Since the present study had limitations, it is necessary to conduct further studies to examine these points.

Conclusion

Immunizations are painful procedures for children that cause considerable pain and anxiety. Watching cartoons and interactive distraction do not seem to be effective in reducing high levels of pain. Nursing staff should explore different forms of play and interaction which can effectively reduce children's pain before procedures.

Acknowledgements

The authors are grateful to all participants who greatly contributed to this study and the collaboration of one medical doctor, Dr. Tadashi Imai. We also would like to thank Rie Shinomiya and Sonoko Mori (Department of Nursing, Kagawa University Hospital) for rating the FLACC score.

References


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Received Date: April 19, 2015, Accepted Date: July 24, 2015, Published Date: August 03, 2015.

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