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Comparing the effectiveness of two distraction techniques of inflating balloon and watching cartoon in reducing the vaccination pain among school-age children

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ABSTRACT

Background: The pain caused by the invasive procedures, such as vaccination, could be associated with mental tension and tissue damage in children. Therefore, one of the priorities of the healthcare providers is to manage this pain. Regarding this, the present study aimed to evaluate the effect of distraction using inflating balloons and watching cartoons on the intensity of the pain induced by diphtheria tetanus and pertussis (DPT) vaccine in school-age children.

Methods: This clinical trial was conducted on the school-age children, who referred to Sayyid Al-Shuhada Healthcare Center in Zahedan, Iran, in 2015. In total, 120 patients were selected through convenience sampling technique. The subjects were randomly divided into three groups of 40 cases. The participants of the first group were encouraged to inflate balloons throughout the vaccination process. On the other hand, the subjects of the second group watched a cartoon started two min before the vaccination and lasting to the end of this procedure. No intervention was carried out for the control group. The pain intensity was measured immediately after the vaccination using the Face, Legs, Activity, Cry, Consolability scale (FLACC scale). The data analysis was performed in the SPSS version 22 using the descriptive statistics and one-way ANOVA test.

Results: In this study, the mean pain scores were 1.87±1.30, 1.40±0.87, and 3.22±1.38 in the first, second, and control groups, respectively. The results of the ANOVA test revealed a difference between the study groups regarding the pain intensity ($P<0.001$); however, this difference was not significant.

Conclusion: According to the findings of this study, two distraction methods of inflating balloon and watching cartoons could effectively decrease the pain induced by DPT vaccine. Therefore, the use of these techniques is recommended to manage the pain in children since they are inexpensive and have no side effects.

1. Introduction

One of the main objectives of public health is the prevention of diseases using vaccination, which controls a hundred million illnesses and million deaths.[1] Nevertheless, vaccination through injection is one of the most common invasive techniques used in the current modern world, which is painful for children and is repeated several times during a person's lifetime.[2]

Based on the national vaccination program of Iran, a child receives 10 vaccines until the age of six years in this country.[3] This recurring pain is a great source of anxiety and stress for the majority of children, mainly due to the fact that the experience of pain causes the child to predict the vaccination pain, get stressful, and consequently show physiological symptoms and uncooperative behaviors such as crying.[4]

The pain caused by vaccination is not only distressing for the child, but also may cause problems for the parents and healthcare providers to complete the vaccination process.[5] Sometimes, the healthcare personnel might need to hold the child tightly and keep him/her immobile to inject the vaccine, which is often associated with adverse effects on future injection procedures and other health cares.[6-8] Therefore, one of the most important responsibilities of the healthcare personnel is to effectively control the pain. Regarding the humanitarian beliefs and principles in physiology or

medicine, the prevention of the pain is better than its treatment. It is essential to use the easy, efficacious, cost-effective, and efficient techniques to relieve the pain and prevent its adverse outcomes.[9]

In this regard, the pharmacological methods include analgesics (e.g., acetaminophen, ibuprofen, opioids) and EMLA cream.[9, 10] On the other hand, the non-pharmacological techniques are application of sweet solutions, such as sucrose and glucose,[11-13] breastfeeding,[13-15] skin contact,[12, 16] use of cold compress,[17] and distraction.[18, 19] However, the respective strategy should be tailored to the child's age and pain severity.[20]

Today, the non-pharmacological methods have been mostly taken into consideration by the healthcare system and patients.[21, 22] Accordingly, the distraction technique is regarded as a non-pharmacological and non-invasive method, which could be an attractive technique for children to decrease their pain severity if implemented appropriately with regard to the child's age.[18, 19]

The distraction techniques or other similar methods are often provided in two active or inactive types based on the age range of the patients. While in the active distraction method, the children are involved in the distraction process, in the inactive method, they act passively.[23] The literature review demonstrated that the majority of the previous studies investigated the pain caused by vaccination in the newborns using the inactive techniques.[7, 24] However, the studies evaluating the effect of the active distraction technique on children revealed the positive effects of this method on the pain caused by venipuncture and other acute pains.[5, 23]

Therefore, given the positive effects of distraction on pain control and with respect to the fact that the majority of the studies in this area have been conducted on newborns, this study aimed to compare the effect of two distraction techniques (i.e., balloon inflation and watching cartoons) on the severity of pain caused by diphtheria, pertussis, tetanus vaccine among the school-aged children.

2. Methods

2.1. Design

This clinical trial was conducted on the school-age children, who referred to Seyed Al-Shohada Healthcare Center in Zahedan, Iran, in 2015.

2.2. Participants and setting

Based on a study conducted by Hadadi et al. (2011)[7], the sample size was estimated to be 40 individuals per group (total=120 subjects) with 5% error and 90% power (Z_{β}=1.28, δ=1, β=0.1, d=0.7). The patients were selected using the convenience sampling technique within May 2014-June 2014.

The participants were divided into two intervention groups (i.e., balloon inflating and watching TV) and one control group using the simple random allocation method. To do so, the researcher wrote "I1", "I2", and "C" phrases, representing the first (balloon inflating) and second (watching cartoons) interventions and control group, respectively, on colored papers and kept them in a covered package. After introduction and with regard to the research ethics, the children were required to select a card according to which they were entered into the respective study groups.This continued until the completion of the groups.

The inclusion criteria were: 1) no progressive brain injury, epilepsy, and untreated seizure, 2) lack of respiratory disorders, 3) no use of painkillers or sedatives 24 h before the vaccination, 4) lack of mental retardation or inability to communicate, 4) no acute pain during vaccination (e.g., severe pain caused by an illness, such as stomachache) and 5) having eaten breakfast. On the other hand, the exclusion criterion was lack of child cooperation.

2.3. Instruments

The research tools consisted of the demographic form (e.g., age and gender) and the Face, Legs, Activity, Cry, Consolability scale (FLACC).

The reliability and validity of the FLACC scale were confirmed by Voepel-Lewis et al. (1997) at Michigan University. This scale facilitates the evaluation of the changes in the face, legs' position, activities, cry, and consolability of the children. The scoring of each section ranges from zero to two, which are indicative of the child's lack of reaction and maximum reaction to the stimulator and pain, respectively. In total, this scale is scored within the range of 0-10, according to which the scores of 0-3, 4-7, and 7-10 indicate mild, medium, and severe pain, respectively.[25] The reliability of this tool was confirmed in a study carried out by Voepel et al. (2003) using inter-rater observation technique (r=0.94) and Cohen Kappa coefficient (r=0.82).[26, 27] This scale was also confirmed in Iran by Sadeghi et al. (2013), rendering a correlation coefficient of 0.70.[28] In the present study, the reliability of the mentioned tool was confirmed using interrater reliability. To do so, the pain caused by vaccination was simultaneously evaluated in 15 children by two observers, and the correlation coefficient between the observers' scores were assessed (r=0.73).

2.4. Data Collection

In order to perform the intervention in the first group, the children were encouraged to inflate a

balloon starting from 60 sec prior to the vaccination to the end of the process. In the second group, the children watched a cartoon on a laptop begun two min before the vaccination and lasting to the end of this process. On the other hand, in the control group, the children given the vaccine without receiving any intervention. The intramuscular injection was carried out for all three groups under identical conditions using similar instruments by the selected personnel of the healthcare center. After the disinfection of the injection site with an alcohol soaked cotton, the vaccine (0.5 cc) was given via the intramuscular route into the deltoid muscle using a 2 ml syringe (needle length and gauge: 5.2 cm and 23, respectively). The vaccination was quickly performed within 2-3 sec by no aspiration, followed by rapid needle withdrawal.[3]

2.5. Ethical considerations

In line with the ethical considerations, the research objectives were explained face-to-face to the mothers of the participants in their presence. Furthermore, they were informed about the possibility to withdraw from the study at any time without any effect on the vaccination process. In addition, the researcher was available throughout the study and answered all the questions. The written informed consents were obtained from the mothers prior to the study.

2.6. Statistical analysis

The data analysis was performed in the SPSS version 22, using the descriptive statistics (mean and standard deviation) and one-way ANOVA (to evaluate the difference between the mean scores of the participants).

3. Results

The demographic characteristics of the participants are provided in Table 1. According to this table, no significant difference was observed between the intervention and control groups regarding the studied variables. None of the groups experienced severe pain after the vaccination. The highest pain score was related to the control group, in which 47.5% of the subjects experienced medium pain (Table 2).

The mean scores of pain caused by triple vaccination were 1.87±1.30, 1.40±0.87, and 3.22±1.38 in the first, second, and control groups, respectively. The results of the ANOVA test indicated a statistically significant difference between the three groups regarding the mean pain intensity (P<0.001). In addition, the post-hoc Tukey test demonstrated that the control group had a significant difference with the distraction techniques of balloon inflating (P<0.001) and watching cartoon (P<0.001). However, no significant difference was observed between the two intervention groups in this regard (P=0.189).

Table 1. Demographic characteristics of the participants

Variables	Groups	Balloon inflating	Watching cartoons	Control	P-value
		N(%)	N(%)	N(%)	
Gender	Male	25(62.5)	22(55)	25(62.5)	*0.41
	Female	15(37.5)	18(45)	15(37.5)	
Age	M±SD	76.27±2.81	77.97±3.72	77.75±4.07	**0.65

*Chi-square test; **One-way ANOVA

Table 2. Comparison of the frequency of pain intensity caused by vaccination in the control and the two intervention groups

Groups / Pain intensity	Balloon inflating	Watching cartoons	Control
	N(%)	N(%)	N(%)
Mild (0-3)	35 (87.5)	40 (100)	21 (52.5)
Medium (4-7)	5 (12.5)	0 (0.0)	19 (47.5)
Severe (8-10)	0 (0.0)	0 (0.0)	0 (0.0)

4. Discussion

According to the results of the current study, the pain reduction was higher in the group distracted with watching cartoons, compared to the other two groups. In addition, the pain intensity was lower in the balloon inflating distraction technique than that in the control group. In this regard, Gedan et al. (2013) reported that the infants who were distracted by a light and sound producing toy had higher pain intensity, compared to those distracted with cartoons. However, they reported that the two intervention groups experienced less pain, compared to the control group.[29] The results of the mentioned study are in congruence with our findings. It seems that various sensory stimuli could intervene with pain transmission to higher nerve centers.

In another study conducted by Law et al. (2011), the children with passive roles in the distraction group experienced more pain, compared to those with active roles.[30] These results are inconsistent with the results of the current study, which might be due to the type of experienced pain in addition to the subjectivity of the pain. In the study by Law et al., the pain was induced in children using coldness.

In line with the results of the present study, various studies have indicated that distraction could have a positive impacts on reduced vaccination pain. In this regard, Younesi et al. (2014) used moving toys within the period of before to after injection, which resulted in reduced vaccination pain in the newborns.[24] Haddadi Moghadam et al. (2011) recognized the use of distraction technique of shaking rattles to be effective in reducing the pain caused by the vaccination in the infants.[7] Kheirkhah et al. (2011) also reported that using rattles led to lower vaccination pain in the newborns of the intervention group, compared to the subjects of the control group.[31] Furthermore, the results obtained by Talwar et al. (2014) indicated that using the light and sound producing toys could be used as an effective distraction technique to reduce the vaccination pain.[4]

The majority of the studies investigating the effects of the distraction technique on reducing the vaccination pain have been conducted on the newborns; however, their results are in accordance with our findings. Nevertheless, given the fact that the school-age children have more complete sensory information processing system, it is essential to use such distract techniques, which engage all their six senses as far as possible.[32]

Therefore, the reason of observing various pain intensities in different studies might be due to the differences in the reactions of the children and infants in this regard. There are multiple complicated factors, such as genetics, evolution, and experience, affecting the pain reaction. In addition, the pain can be a factor for strengthening the child's reaction. On the other hand, the mean pain intensity obtained in the present study, both in the control and the two intervention groups, were lower than those reported in the aforementioned studies. Our participants had better understanding and more experience, compared to those of the other studies, which mostly involved newborns. This issue might have affected the final results.

One of the major drawbacks of this study was the measurement of pain intensity only through observation; however, pain is a mental variable. On the other hand, some of the children might have been extroverts and some introverts and try to control their emotions, which limits the final results. In addition, different behavior of parents for reducing the pain of their children during vaccination was one of the limitations of this study, which could not be controlled by the researcher.

5. Conclusion

As the findings of the present study indicated, both distraction techniques (i.e., balloon inflating and watching cartoons) had significant impacts on reduced pain caused by triple vaccination in school-age children. Therefore, these techniques are recommended to be used as standard care techniques during the vaccination since they are cost-effective and have no complications. Moreover, providing retraining programs for familiarizing the healthcare providers with non-pharmacological methods to relieve pain seems necessary.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Hassan Robabi: study design, data analysis, data collection, participation in drafting of the manuscript, Hassan Askari: participation in drafting of the manuscript, Farshid Saeednegad: participation in data analysis, drafting of the manuscript.

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