Original Article

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The Effect of Manual Pressure Applied on Infants Before Vaccine Injection on Pain Level and Crying Time

Aşı Enjeksiyonu Öncesinde Bebeklere Uygulanan Manuel Basıncın Ağrı Düzeyi ve Ağlama Süresine Etkisi

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ABSTRACT

Objective: The aim of this study was to determine the effect of manual pressure applied to the injection site before vaccine injection on the level of pain and crying time of 4-month-old infants.

Methods: This study was a randomized controlled trial. The sample of the study included 70 infants (35 infants in the intervention and 35 in the control groups). Research data were collected using an "Information Form", the FLACC Pain Assessment Scale, and a stopwatch. Before the procedure, manual pressure was applied to the injection site with the thumb for 10 seconds to the infants in the intervention group. No non-pharmacological method was applied to the infants in the control group before vaccination. Pain scores of the infants were evaluated during and after the vaccine injection, and total crying times were recorded.

Results: It was found that the pain score of the control group (6.37±1.92) was higher than that of the intervention group (4.40±2.32) ($p<0.05$) during the procedure. The pain score of the control group after the procedure (6.86±1.97) was significantly higher than the intervention group (3.00±2.00) ($p<0.05$). The mean crying time of the infants in the intervention group (5.68±5.54 seconds) was significantly shorter than the infants in the control group (81.67±31.31 seconds) ($p<0.05$).

Conclusion: In this study, manual pressure applied before injection was found to be effective in reducing the pain of infants. Manual pressure is an easy-to-apply, non-time-consuming, and cost-effective method.

Keywords: Infant, injection, pain, manual pressure, vaccine

ÖZ

Amaç: Bu araştırmanın amacı 4 aylık bebeklerde aşı enjeksiyonu öncesinde enjeksiyon bölgesine uygulanan manuel basıncın bebeklerin ağrı düzeyine ve ağlama süresine etkisini belirlemektir.

Yöntemler: Bu çalışma randomize kontrollü deneysel desende gerçekleştirildi. Araştırmanın örneklemini 70 bebek (müdahale grubu: 35 bebek; kontrol grubu: 35 bebek) oluşturdu. Araştırma verileri "Bilgi Formu", FLACC Ağrı Değerlendirme Skalası ve kronometre aracılığı ile toplandı. Müdahale grubundaki bebeklere işlemden önce enjeksiyon bölgesine 10 saniye süre ile baş parmak ile manuel basınç uygulandı. Kontrol grubundaki bebeklere aşı uygulaması öncesinde herhangi bir non-farmakolojik yöntem uygulanmadı. Bebeklerin aşı enjeksiyonu sırası ve sonrasında ağrı puanları değerlendirildi ve toplam ağlama süreleri kayıt edildi.

Bulgular: İşlem sırasında kontrol grubunun (6,37±1,92) ağrı puanının müdahale grubundan (4,40±2,32) daha yüksek olduğu bulundu ($p<0,05$). Kontrol grubunun işlem sonrasındaki ağrı puanının (6,86±1,97), müdahale grubuna göre (3,00±2,00) anlamlı olarak yüksek olduğu belirlendi ($p<0,05$). Müdahale grubundaki bebeklerin ortalama ağlama süresinin (5,68±5,54 saniye), kontrol grubundaki bebeklere göre (81,67±31,31 saniye) anlamlı düzeyde kısa olduğu saptandı ($p<0,05$).

Sonuç: Bu araştırmada enjeksiyon öncesi uygulanan manuel basıncın bebeklerin ağrısını azaltmada etkili olduğu belirlendi. Manuel basınç uygulaması kolay, zaman almayan ve maliyet-etkin bir yöntemdir.

Anahtar Sözcükler: Bebek, enjeksiyon, ağrı, manuel basınç, aşı

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Introduction

Vaccination is a routine public health practice recognized worldwide to protect against infectious diseases (1). Many diseases and deaths have been prevented after the advent of vaccines (2). An average of 21 vaccine injections given are made during infancy, although the number of injections is now less as a result of the combined vaccines (3). It is estimated that an average of 12 billion injections are made annually, of which approximately 5% are for infant vaccination (4). The implementation of vaccines and vaccination programs has been significant progress in public health practices. On the other hand, vaccine injection is one of the most common causes of pain in healthy infants and children (5). Parents may avoid or delay vaccination to avoid the pain their child experiences repeatedly with vaccination. Avoiding or delaying vaccination by parents may lead to disruption of vaccination programs, and thus to an increase in communicable diseases preventable by vaccination. Management of pain from vaccine injection in children is therefore very important (6,7).

Non-pharmacological methods are frequently preferred all over the world because they are effective in reducing the pain of children when used alone or in combination with pharmacological methods (8). There are studies examining the effects of non-pharmacological methods such as breastfeeding, oral sucrose, appropriate positioning, distraction, massage, manual pressure application, and the use of appropriate injection techniques in the control of pain during vaccination in children (1,2,5,7,9,10). One of these methods, manual pressure is applied to the injection area with the thumb for 10 seconds before the injection (11). Only limited studies examining the effect of manual pressure on the pain caused by vaccine injection in infants could be identified (9). Considering this important deficiency in the literature, the study was carried out to determine the effect of manual pressure applied to the injection site on the pain level and crying time of infants before the injection of the 5-in-1 vaccine [diphtheria-tetanus-acellular pertussis inactivated poliomyelitis and Haemophilus influenzae type B (DTaP-IPV-Hib)] in 4-month-old infants.

Research hypotheses:

Hypothesis 1 (H1): The pain scores of the infant's given manual pressure before the vaccine injection are lower than the infants who are not.

Hypothesis 2 (H2): Infants who are given manual pressure before vaccine injection have shorter crying times than infants who are not.

Methods

Study Design and Participants

This randomized controlled study was conducted between December 2021 and April 2022. The study followed the CONSORT (Consolidated Standards of Reporting Trials) checklist. The population of the study included 4-month-old infants who were brought to a family health center to have the 5-in-1 vaccine (DTaP-IPV-Hib). The sample size of this study was calculated by power analysis in G*Power 3. 1.9.4 program based on a study (5), which reported that the aspiration-free and rapid injection technique applied during vaccine injection was effective in reducing pain scores in infants aged 6 weeks to 6 months. Taking the effect size as 0.67 for the FLACC pain score, the sample size was calculated as 66 infants in the sample size analysis performed by taking the alpha error probability of 0.05 and the power value of 0.85. Considering that there may be drop-outs from the sample, it was decided to carry out the study with a total of 70 infants, 35 in both groups. As the inclusion criteria, the infants had to be healthy and born at term, had to be 4 months old, had to be receiving the 5-in-1 vaccine (DTaP-IPV-Hib), should not have any chronic conditions or a neurological disorder which might affect the infant's response to pain and should not have received an analgesic within 24 hours before vaccination.

Randomization of the study was done through an online program with the URL https://www.random.org/. Lots were drawn before the sample number was entered into the software, and the 1st set was assigned to the control group and the 2nd to the intervention group. To determine the assignment of the infants included in the study to the groups, numbers from 1 to 70 were written into the software without repeating the numbers. The infants forming the sample group were randomly distributed to the two groups by the software.

Data Collection Instruments

Information form, FLACC Pain Assessment Scale, and stopwatch were used to collect the research data.

Information form: It consisted of 11 questions on the socio-demographic descriptive characteristics (age, gender, etc.) of the infants included in the study and their parents. The form also included spaces to record FLACC pain scores and total crying times.

FLACC Pain Assessment Scale: The pain of infants in the intervention and control groups was evaluated using the "FLACC Pain Assessment Scale" in the study. It was developed by Merkel et al. (12) in 1997 to assess the pain of children aged 2 months to 7 years. The child's facial expression, leg movements, activity, crying, and consolability behaviors are evaluated in relation to pain. These five behaviours are rated with 0, 1, or 2 points. The total score of the scale ranges from 0 to 10, with high scores indicating that the child has pain. A score of "0" from the scale indicates no pain, "1-3" points indicate mild pain, "4-6" points indicate moderate pain, and "7-10" points indicate severe pain (13,14). The FLACC scale was translated into Turkish in the study by Şenaylı et al. (15) evaluating the pain of children aged 1 month to 9 years.

Stopwatch: Voit 8073 stopwatch was used to determine the crying times of the infants included in the study.

Procedures

Parents of infants who met the inclusion criteria were informed by the researcher about the study, and their verbal and written

consent was obtained. Information about the infants included in the study and their parents were recorded in the "Information Form" 5 minutes before the procedure by face-to-face interview method by the researcher. The same nurse researcher did all the vaccinations. The infant was laid back, and the vaccination area was marked. The 5-in-1 vaccine (DTaP-IPV-Hib) was intramuscularly (IM) injected. The injection site was at the right or left laterofemoral section of the vastus lateralis muscle, which was in the middle 1/3 part of the thigh. The vaccination area was disinfected with alcohol, and the vaccine was injected into the vastus lateralis muscle at a 90-degree angle.

All infants were awake and had clean diapers at the time of injection, and their parents were present in the procedure room. No non-pharmacological method was applied to the infants in the control group before vaccination, and routine vaccination was performed. Before the procedure, the infants in the intervention group were applied manual pressure to the injection site with the thumb for 10 seconds before the procedure. Parents of all infants both in the intervention and control groups were present during the procedure. During vaccination, parents were allowed to calm the infants in both groups by touching and talking to them. They were not allowed to feed and do anything that would distract the infant's attention, including giving them toys, showing them a dummy, or clapping. Once the vaccine was started to be injected, the infants' pain was evaluated by the nurse researcher using the FLACC scale. Immediately after the vaccine injection was ended and the needle was removed, the infants' pain was re-evaluated by the nurse researcher using the FLACC scale. If the infant started to cry, another nurse working at the family health center started a stopwatch and stopped when the infant stopped crying to measure the total crying time of the infant.

Ethical Considerations

This study was registered in the clinical trial registry (ClinicalTrials.gov number: NCT05143450). Ethical approval was obtained for the study from Biruni University Clinical Research Ethics Committee (decision no: 2015-KAEK-53-21-02, date: 29.09.2021). Before starting the study, the parents of the infants included in the study were informed about the purpose, duration, plan of the study, and where and how the obtained data would be used. In line with the principles of voluntariness and willingness, verbal and written consent were obtained from the parents.

Statistical Analysis

Data were evaluated with the SPSS package program for Windows (version 21, IBM Corporation, Armonk, NY). In evaluating the data, number, percentage, mean and standard deviation were given in descriptive statistics. Paired t-test was used to evaluate repeated measures of normally distributed variables and independent t-test to compare paired groups. For variables not showing normal distribution, Wilcoxon test was used to evaluate repetitive measurements, Mann-Whitney U test to compare paired groups. A p-value of $p<0.05$ was considered statistically significant.

Results

In this study, 78 infants were assessed for eligibility. Before randomization, 8 infants were excluded because their parents declined to participate. A total of 70 infants were assigned into groups (35 in the intervention and 35 in the control group) (Figure 1). Of the infants, 60% in the control group and 54.3% in the intervention group were boys, and the majority of the infants in both groups (65.7% for both groups) were born into a nuclear family. The mean age of the mothers of the infants in the intervention group was 27.20±6.63 years, and the mean age of the fathers was 31.97±5.89 years. The same values for the control group were 26.97±5.14 and 30.57±5.94 years, respectively. The two groups were well-matched in their descriptive characteristics ($p>0.05$).

The pain score of the control group (6.37±1.92) during the procedure was found to be significantly higher than the intervention group (4.40±2.32) ($p<0.05$). The pain score of the control group (6.86±1.97) after the procedure was found to be significantly higher than the intervention group (3.00±2.00) ($p<0.05$) (Table 1, Figure 2). The mean crying time of the infants

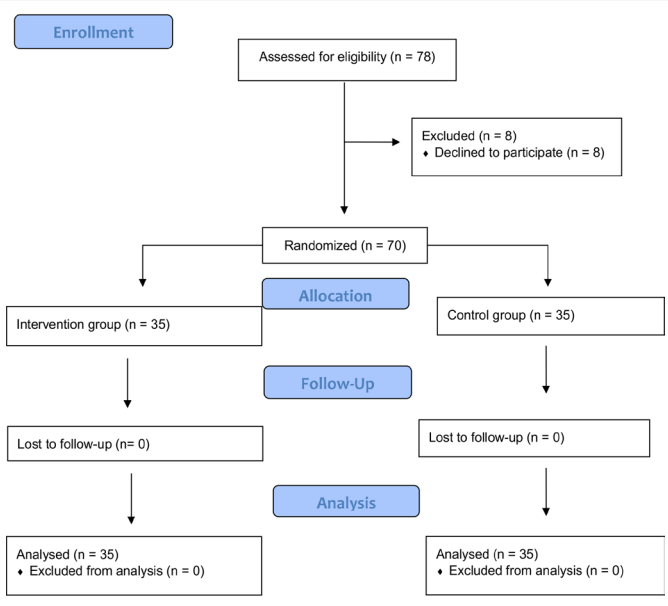

Figure 1. CONSORT participant flow diagram

Table 1. Comparison of mean FLACC scores during and after injections between the intervention and the control groups (n=70)

Time	Intervention group (n=35) M ± SD (Median)	Control group (n=35) M ± SD (Median)	U*	p-value
During injection	4.40±2.32 (4)	6.37±1.92 (5)	321.00	0.00
After injection	3.00±2.00 (4)	6.86±1.97 (7)	115.00	0.00

M: Mean score, SD: Standard deviation, *Mann-Whitney U test

in the intervention group was 5.68±5.54 seconds, compared to 35.57±39.57 seconds in the control group. The crying time of the infants in the intervention group was significantly shorter than the control group ($p<0.05$) (Table 2). The intervention and control groups did not differ statistically significantly by gender for the mean FLACC score and the mean crying time during and after the procedure ($p>0.05$) (Table 3).

Discussion

Although early childhood injectible vaccines are vital for preventive health, they are painful and often lead to fear of needles. Recent research has recommended updating evidence-based strategies for managing pain associated with vaccine injections using non-pharmacological interventions (6). Using such interventions could reduce pain and could easily become a routine aspect of the delivery of vaccine injections (16). The results of our study revealed that manual pressure was effective in pain relief in the infants administered DTaP/IPV/Hib.

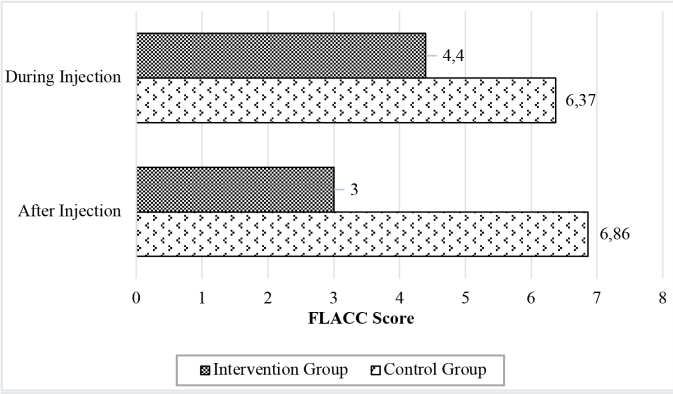

Figure 2. FLACC scores of the groups during and after the injection

Table 2. Comparison of mean crying time between the intervention and the control groups (n=70)

Crying time	Intervention group (n=35) M ± SD (Median)	Control group (n=35) M ± SD (Median)	U*	p-value
Crying time (second)	5.68±5.54 (5)	35.57±39.57 (18)	190.500	0.00

M: Mean score, SD: Standard deviation, *Mann-Whitney U test

One of the most obvious and observable behavioral responses of infants to painful stimuli is crying (17). Both the intensity (e.g., gentle or whimpering) and duration of crying are valid measurements (18). Crying time in infants is used to determine the time, severity, and duration of pain (16). In our study, the infants in the intervention group had a shorter crying time. In a study examining the effect of rapid injection without aspiration and applying 10 seconds of manual pressure in infants aged 4-6 months who were administered the 5-in-1 vaccine (DTaP-IPV-Hib), the average pain score of the infants in the manual pressure group was lower than the infants in the control group. In the same study, the mean crying time of infants in the manual pressure group (10.8±21.8) was shorter than that of the infants in the control group (27.3±27.9) (9).

The pain control effect of manual pressure is explained by the gate control theory (19). According to this theory, the presence and severity of pain depend on the transmission of neurological stimuli. Briefly, if the gate is open, the stimulus reaches the level of consciousness and pain is felt, and if it is closed, the stimulus does not reach consciousness and pain is not felt (20). Applications such as rubbing the pain area, pressing with fingers, and massage provide closing the gate to painful stimuli (11). Studies examining the effect of manual pressure on pain associated with intramuscular injection in different age groups found this method to be effective in reducing pain (11,19). In a study examining the effect of manual pressure to the IM injection area before penicillin injection on the pain level of children aged 7-19 years, the pain scores of children who were applied manual pressure were significantly lower than the children in the control group (11). Chung et al. (19) conducted a study with 74 students between the ages of 18-21 to investigate the effect of manual pressure application on pain in Hepatitis A and Hepatitis B vaccine injections and reported significantly lower pain scores of individuals who were subjected to pressure. These data indicate that manual pressure is an effective, easy to apply and cost-effective method not requiring preparation to reduce the pain of intramuscular injection.

Table 3. Comparison of the mean FLACC scores and crying time of the groups according to gender (n=70)

Variables	Intervention group (n=35)		Control group (n=35)	
	Girl (n=16) M ± SD	Boy (n=19) M ± SD	Girl (n=14) M ± SD	Boy (n=21) M ± SD
Pain/during injection	3.56±2.5	5.10±1.9	6.79±2.1	6.09±1.8
U*; p-value	96.00; 0.066		117.50; 0.325	
Pain/after injection	2.62±2.3	3.32±1.7	6.86±2.1	6.81±1.9
U*; p-value	128.00; 0.441		141.50; 0.855	
Crying time	4.44±5.3	6.74±5.6	41.71±46.8	31.48±34.5
U*; p-value	116.500; 0.243		136.50; 0.727	

M: Mean score, SD: Standard deviation, *Mann-Whitney U test

Features such as age, gender, previous painful experiences, and cultural background have been suggested as factors that increase or alleviate the effect of painful experiences in children (2). Gender differences also have complex effects on pain perception. Pain perception can also be affected by biological, psychosocial and other factors such as the intensity, frequency, and duration of pain (21). Gender differences were reported to be effective on pain only during adolescence, not affecting pain in younger children (infants, toddlers, school children) (22). Similarly, in our study, the pain scores and crying times of the infants in both groups were not affected by gender. In the study conducted by Göl and Altuğ Özsoy (9), the average pain score and crying time of infants were similar in infants of both genders, and gender was not a factor affecting pain.

Study Limitations

There were some limitations of the study. One of the limitations was that the study was limited to intramuscular vaccine injection only and was not necessarily generalizable to manual pressure prior to other intramuscular injections such as medication administration. The second limitation was that the observer, who was one of the researchers, conducted pain assessment on both groups. This might pose a natural bias in the observer's outcome. The last limitation of this study was that the previous painful stimuli of the infants were not recorded.

Conclusion

The results of our study indicated that the pain intensity of the infants who were applied manual pressure to the injection area for 10 seconds before vaccination was reduced. Thus, manual pressure before vaccination can be effective in reducing pain and shorten the duration of infant crying during vaccination. Finally, 10-second manual pressure before vaccination can be easy, quick, safe, and inexpensive method to implement in addition to other techniques in the management of vaccine pain.

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Ethics

Ethics Committee Approval: Ethical approval was obtained for the study from Biruni University Clinical Research Ethics Committee (decision no: 2015-KAEK-53-21-02, date: 29.09.2021).

Informed Consent: Verbal and written consent were obtained from the parents.

Authorship Contributions

Surgical and Medical Practices: Z.E., S.K., F.D., Concept: Z.E., S.K., F.D., Design: Z.E., S.K., F.D., Data Collection or Processing: F.D., Analysis or Interpretation: S.K., Literature Search: Z.E., Writing: Z.E., S.K.

Conflict of Interest: No conflict of interest was declared by the authors.

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Trial registration: This study was prospectively registered with ClinicalTrials.gov (NCT05143450).

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